AGRICULTURE, RURAL DEVELOPMENT, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2004

THURSDAY, MAY 22, 2003

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:40 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Robert F. Bennett (chairman) presiding.

Present: Senators Bennett, Cochran, Craig, Kohl, Dorgan, and Johnson.

DEPARTMENT OF AGRICULTURE

STATEMENT OF ERIC M. BOST, UNDER SECRETARY FOR FOOD, NUTRITION, AND CONSUMER SERVICES

ACCOMPANIED BY:

ELSA MURANO, UNDER SECRETARY FOR FOOD SAFETY

WILLIAM T. HAWKS, UNDER SECRETARY FOR MARKETING AND REGULATORY PROGRAMS

Senator BENNETT. The subcommittee will come to order. I apologize to our witnesses and to those who have come to hear them for the fact that we are a bit late. It reminds me, very early in my Senate career, we were having a meeting and I said to my secretary, "Unless the White House calls, we don't want to be interrupted." And a few minutes later, she came in and said, "You are not going to believe this, but the White House is calling."

So this morning, we had the President of the United States speaking to us and that is what caused the delay, and I assure you, it would require something of that level to cause us not to be prompt and we apologize to you.

We appreciate very much the witnesses who are coming. This will be our final budget hearing. We have heard from the other under secretaries of the Department of Agriculture as well as from Secretary Veneman and it has been a very interesting series of hearings, and for me, coming new into this assignment, very informative, and I am very grateful and expect we will have the same kind of exchange here this morning.

We do meet against the background of considerable concern, and I think we ought to use the hearing as a forum for addressing this concern. It has been on the front page of the newspapers and in the lead of various television shows, talking about bovine spongiform encephalopathy. For those that don't recognize that,

and I will refer to it from now on as BSE, that is what the press has labeled "mad cow" disease.

We should understand as we hold this hearing to talk about the safety of food in the United States that BSE has been discovered in a single cow in Alberta, Canada. We should applaud the USDA as well as the Food and Drug Administration for their diligence in monitoring this situation, and it is critical that USDA and FDA provide the public with a clear and consistent message. But I believe that message is being applied and we need to underscore it here today.

The disease has been detected, it is being monitored, and the determination of the various agencies involved is to see to it that the United States is protected from the disease. We should also understand that the way the animal who had this, had BSE, was disposed of guarantees that it will not get into human consumption. There may be some tiny, tiny risk to animals, but there is no risk whatsoever to human beings as a result of this situation. That is at least the way it has been explained to me. If there is any correction that needs to be made, I would appreciate it if our witnesses would correct it.

But the American consumer takes for granted that her food is safe. Sometimes they take for granted too much and do not give appropriate credit to people at the USDA and at FDA who continually monitor the safety of food and the domestic food supply. Their work goes unnoticed until some kind of emergency like this comes along. We should take this occasion, first, to assure the American people that their food is safe, and second, to pay tribute to those who monitor the situation 24/7 so that the American consumer can take it for granted that the food is safe.

We will spend more time on that in the hearing this morning. But as the hearing begins, I wanted to make that front statement so that those who come for the opening of the hearing and then rush to meet their deadlines will at least take away the understanding that the discovery of BSE in a single cow in Alberta, Canada, is not reason for everybody to panic, to give up hamburgers or whatever else might be on their agenda for their food consumption.

With that, Senator Craig, we would be happy to have whatever opening statement you might have.

Senator CRAIG. Mr. Chairman, I will be brief, but I do believe it is an opportunity to talk about the issue that you have opened with this morning and I think it is important that we visit it. I am pleased to see Dr. Murano here with Food Safety and that is appropriate that we talk about BSE.

I think it is important to say several things about it straightaway, and that is that we have been at the business of monitoring and watching this very, very closely for a long while. As we have been able to successfully declare our country clean of this, there is a reason for that, and I think the Department of Agriculture and USDA can be proud of that fact. We started a surveillance program in 1990, I believe, and moved forward and successfully banned when other countries have found that their herds were infected by it.

One animal in Canada now, destroyed, did not get into the food chain, and other animals apparently destroyed that were with or in the same herd.

Now, having said that, it is also important to say that BSE agent is not found in meat. Let me repeat that. It is not found in meat. It is found in the central nervous system tissue, such as brains and spinal cord and others. Those are not incorporated in hamburger or in a New York strip and it is important that we constantly repeat that. By the way, I had a nice piece of filet last night and it was well prepared and I enjoyed it.

It is not a time for this country to panic. It is a time for this country to express some concern and to review it, as you plan to, and for us to review our systems. I have several questions I want to ask as it relates to the ban that we moved quickly to do with Canada on products coming in until such time as determinations are made. That sounds to me like the action taken appropriately. It is not something that we have dawdled about. It is something we have been involved in for a long time.

What I think is important for this committee and for the record, Mr. Chairman, is that we at least affirm that and move forward based on what we know so that the American people can have a degree of confidence in, beyond current levels, their meat supply. What is important is for them to have a great deal of confidence in the broad sense that our foods in this country are safer and better prepared to arrive at the consumer's shelf than nearly any country in the world, and for that, we ought to be proud. Thank you.

Senator BENNETT. Thank you very much.

Senator Kohl.

Senator KOHL. Thank you, Mr. Chairman, for holding this propitious hearing this morning. I would like to welcome our witnesses again to this hearing, which turns out to be of some considerable importance, and a hearing that the American public will be very much interested in hearing what you have to say.

I don't plan on making a long opening statement, but considering the announcement of BSE from Canada just this past Tuesday, this is clearly an important moment. Three of the most important Federal agencies regarding this particular issue are all in the same room together today and each of you play a key role in keeping our food supply safe and preventing diseases, such as BSE, from entering our country.

Therefore, I would like to request that each of you address this issue in your opening statements and use this hearing as a forum to explain to the American eating public, which, after all, is everybody in our country, what this announcement means. Questions like how serious is this issue? What precautions are being taken? Should we, in fact, really be afraid? I think the American people need some answers, and this hearing will provide a unique opportunity for you to address them.

With that, I welcome you again and turn back to our chairman.

Senator BENNETT. Thank you, Senator Kohl.

Senator Johnson.

Senator JOHNSON. Thank you, Mr. Chairman and Senator Kohl. I want to welcome Under Secretary Hawks, Under Secretary Bost,

Under Secretary Murano today, as well as FDA Commissioner McClellan.

We have a lot of timely and important issues to discuss, including one, implementation of country of origin labeling with Under Secretary Hawks. Secondly, the recent case of BSE in Canada, which deals with food safety, Under Secretary Murano, and FDA's ban on animal parts in ruminant feed with FDA Commissioner McClellan.

Given the development of new drugs, advanced medical devices, and other products, I look forward to Commissioner McClellan's analysis of how these products can be made available to the public. And finally, the authorization of child nutrition programs are key.

Let me address just very briefly the country of origin implementation issue. I know that Under Secretary Hawks has personally attended a number of the USDA listening sessions and I hope that USDA keeps an open mind about finding a reasonable method to, in good faith, implement country of origin labeling, because as written, the law permits USDA to use a great deal of discretion to implement labeling and model existing programs—school lunch, USDA grading system, certified Angus beef system, and so on, that have proven effective, workable, and inexpensive.

Nevertheless, very frankly, there is a widely-held belief that is growing in rural America that the Department of Agriculture is not about to, in good faith, implement country of origin labeling and we need to disprove that and to make this system work, make it work effectively and inexpensively. I am concerned that some in USDA seem all too willing to create a new, unnecessary bureaucratic recordkeeping regime so that labeling will implode under its own weight before it is even implemented.

Some hard-working public servants in the USDA, especially in the Ag Marketing Service, are moving ahead in good faith to implement a common sense country of origin labeling program and I commend these officials. On the other hand, I am very disappointed that some seem to be trying to politicize this effort and to cancel out the progress as we attempt to make implementation work. I hope these strong anti-labeling forces will let the real experts, our career officials at AMS, write a sensible and workable final rule for implementation.

Let me say this about country of origin labeling and BSE. While country of origin labeling obviously does not prevent BSE, that is not the issue. The fact that consumers are unable to differentiate between U.S., Canadian, and beef from other nations is simply unacceptable. Country of origin labeling is not a food safety issue directly, but it is a consumer information issue and it is a consumer confidence issue. I was pleased that today, the Consumer Federation of America expressed their strong support for country of origin labeling.

Let me just quickly touch on the FDA feed ban issue. I worked with Commissioner McClellan about the 1997 rule that feed mills in the United States prevent the commingling of animal proteins in ruminant feed. This has been a concern of mine for some time, largely because contaminated feed consumed by cattle is what we believe is a key causation for BSE in the first place.

When I first began to examine the issue in 2001, I met with Dr. Steven Sundloft, Director of FDA's Center for Veterinary Medicine, and at our meeting, I learned at that time that 13 percent of the feed mills regulated by FDA did not have systems in place to prevent the commingling of animal parts and feed. Furthermore, 15 to 20 percent of the feed mills failed to properly label feed, "not approved for use with ruminants," as such. Moreover, 80 percent of feed mill inspections were handled at the State level. FDA was not even doing most of the inspections.

I believe FDA and the feed industry would agree with me that we should have improved the compliance rate with this rule since 2001. In fact, we ought to get 100 percent compliance. Unfortunately, that goal has not been reached. Consumer groups indicate that, currently, FDA has only ten of its own inspectors and still heavily relies on States to do the majority of the inspections of feed mills and rendering plants.

I hear and I have read reports that as of March 23, inspections revealed that 14 percent of rendering facilities handling material prohibited for ruminant feed still did not have a system to prevent commingling of prohibited and non-prohibited material. Inspections also revealed that 33 percent of non-FDA-licensed feed mills had not labeled their products with the required caution statement about not feeding prohibited materials to ruminants, and that is unacceptable.

GAO recently issued a report stating that FDA had not acted promptly to compel firms to comply with the feed ban rule. In fact, GAO identified some non-compliant companies that have not been reinspected for 2 or more years and instances where no enforcement action had been taken.

Today, I call upon FDA to demand 100 percent compliance and insist that FDA explain the rationale for failing to promptly compel these feed mills to comply. The FDA needs to clarify how many feed mills and renderers are complying with the ban and whether firms are properly labeling prohibited material as such. Furthermore, FDA needs to explain how they will ensure universal 100 percent compliance with the ban, and if the States and/or FDA need further assistance from this committee and from Congress for that purpose.

I look forward to discussion of the medical device and child nutrition issues.

Again, I share the comments of my colleague from Idaho that American consumers can take great confidence in meat products available to them and their families in this country. We have the highest quality, safest food in the world, bar none. There is no cause for panic. There is no cause for excessive concern.

But at the same time, we at the governmental level need to make sure that that confidence is strengthened and that there is no justification for a loss of confidence in the quality of American meat products won by more aggressive action, I believe, on the part of FDA, but secondly, also by empowering American consumers to be able to make knowing choices about whether they are consuming American meat products or not. That is a very simple, inexpensive, easily done effort and I think that we can get there.

I look forward to this hearing today and the insights shared with us by this very distinguished panel, Mr. Chairman.

Senator BENNETT. Thank you. Senator Dorgan.

Senator DORGAN. Mr. Chairman, thank you very much. I am going to have to go to the Commerce Committee, but I want to come back because I want to visit with the FDA. I believe that is the second panel.

Senator BENNETT. Yes, and we have asked the FDA Commissioner to be in the audience during the first panel because I think the combination of FDA and USDA in the present atmosphere is important. While it is an imposition on his time, I want him to hear the first testimony so that he can respond during the second panel.

Senator DORGAN. I think that is an excellent idea and I regret I can't be here during all of it, but we have a hearing I have to be at over at Commerce, so I will be coming back.

But I wanted to mention just one quick point on something I believe Senator Craig has said earlier, and I just heard my colleague from South Dakota say, about our food supply, about mad cow disease. Let me just say that what I heard in the last couple of days about this angers me for one reason. The head was cut off a slaughtered cow in January and we learn in the month of May that that cow had mad cow disease. Four months is an unforgivable amount of time.

I don't know the consequences of all of this, but in this country, we have taken great steps. We made 20,000 tests, examinations, pathologies last year in this country to make sure that we have a safe supply of meat. Nine hundred such examinations were made in Canada last year. I am not suggesting the Canadian meat supply is unsafe, but I am saying that if there is a cow that in January is killed that has mad cow disease, then our country and the Canadians and consumers and the beef industry ought not know about it 4 months later. They ought to know about it 4 or 5 days later.

There are only a couple of explanations for this. One, they knew about it earlier but didn't tell anybody. I doubt whether that is the case. I think that is not the case. It looks like the Canadians thought the cow had pneumonia and they either put the cow's head in a freezer or in some solution. Several months later, somebody drug it out and said, let us take a look at it, tested it, and then sent it off to Britain or to England for more testing.

I think that is gross incompetence. We need to make certain that if there are ever questions about this, that there is testing and it is done aggressively and routinely and we get answers quickly and take actions immediately.

I just got off the phone with the Agriculture Secretary, Ann Veneman, and I told her that yesterday I complimented her. She took exactly the right action. She was decisive and quick. We get a million head of cattle a year from Canada, a billion pounds of beef a year into this country from Canada. She shut it down right now, because at this point, we don't know all of the circumstances. And so I appreciate what she has done. She sent people to Canada immediately to be involved in this, and let us hope that this is one single isolated instance. Let us hope never again will we find that,

in Canada or anywhere else, there is a case of mad cow disease that no one knows about for 4 months. That is unforgivable.

So that is another side of this issue that I don't think my colleague mentioned, but I certainly agree with all of his comments. I did not hear all of Senator Craig's comments, but I think I agree with what I heard he said and I think this timing issue is just critical.

Senator CRAIG. I assure you, you always do agree with me, Byron.

Senator DORGAN. Well, almost always, especially when we are talking about beef.

Senator CRAIG. You have got it.

Senator DORGAN. When we get too far afield of beef, it is not always the case.

But Mr. Chairman, thank you very much for giving me the time.

Senator BENNETT. Thank you.

We will now go to our witnesses. We will hear first from Eric Bost, the Under Secretary for Food, Nutrition, and Consumer Services, followed by Elsa Murano, Under Secretary for Food Safety, followed by William Hawks, Under Secretary for Marketing and Regulatory Programs.

Thank you again for being here and for your service. Mr. Bost.

OPENING STATEMENT OF ERIC M. BOST

Mr. BOST. Good morning, Mr. Chairman, members of the subcommittee. Thank you for this opportunity to present the Food, Nutrition, and Consumer Services budget request for fiscal year 2004. I have two of my staff members with me, Suzanne Biermann, who is Deputy Under Secretary, and also George Braley, who is the Associate Administrator for the Food and Nutrition Service.

You have my written testimony, so I will try to be brief in terms of hitting some of the really important issues that I would like to talk about.

The President's budget for fiscal year 2004 requests $44.2 billion in new budget authority for the Department's nutrition programs. The budget is a clear reflection of the Administration's commitment to the nutrition safety net and to the associated activities President Bush expects us to achieve. The budget is constructed for results and the expectations are very clear. One, ensure access for eligible persons to these critical programs. Two, improve performance and program integrity. Three, address nutritional issues related to the problem of overweight and obesity in this country.

Let us talk about ensuring access, more specifically, the Food Stamp Program. The Food Stamp Program request of $27.7 billion will serve an average of 21.6 million persons each month, including restoration of eligibility to many legal immigrants as provided for in last year's Farm Bill. The Administration's budget continues the $2 billion reserve appropriated last year.

The Child Nutrition Program's request of $11.4 billion supports an increase in school lunch participation from 28 million children to over 29 million children and supports an increase in school breakfast participation of over one million children, from 8 million, which we are averaging this year, to about 9 million.

The President's budget proposes $4.8 billion for the WIC Program to provide food, nutrition, and education and a link to health care to a monthly average of 7.8 million needy women and their children, a very clear sign of the President's commitment as he increased funding the second year in a row for this very critical program. The request also provides for a $150 million contingency fund, which we believe is unprecedented.

One of the issues that is very important to the Secretary and I is to ensure program integrity in our programs. In terms of food stamps, funding to maintain our level of effort to reduce errors in the Food Stamp Program is also included in the President's proposal. The payment accuracy rate for the Food Stamp Program for fiscal year 2001 was 91.34, the best ever accuracy rate in the history of the Food Stamp Program. We will continue to work with our State partners to improve that.

In terms of the WIC Program, the President's request provides for $30 million to support the enhancement and modernization of the WIC State Information Systems that will improve the management of this program, which I believe is long overdue. The President's request also provides for improving the eligibility determination system for the National School Lunch Program.

One of the major issues we face in terms of nutrition in this country is the issue of the number of Americans who are overweight and obese. Sixty-two percent of all Americans in this country are overweight, a significant increase over the course of the last several years. As a part of the President's HealthierUS Initiative, nutrition assistance programs play a critical role in promoting good health and preventing diet-related diseases.

As a part of the President's budget, this priority is clear. Some of the things we are interested in doing include: supporting breastfeeding promotion efforts and other activities in WIC; providing peer counseling and demonstration projects to evaluate how the program can be more efficiently used to combat obesity among our children; expanding the successful "Eat Smart and Play Hard" campaign to other nutrition programs; developing an integrated family-oriented approach to nutrition education that allows the Department to partner with multiple Federal agencies; promoting nutrition to all Americans, including resources to update and promote the Food Guide Pyramid; and one of our most popular programs, funding for both the WIC and Senior Farmers' Market Nutrition Programs.

In conclusion, the President's direction has been very clear. The Administration's request has priorities to ensure access, maintain and improve integrity, and support efforts to address a public health threat of overweight and obesity. And given that we have spent a lot of time this morning talking about it, we truly believe we have one of the safest food programs in the entire world in terms of the foods that we provide to approximately 27 million children every day, as a part of the National School Lunch Program. Also, I would like to note, too, that there is a concerted, coordinated effort among all three of us to ensure that occurs on a daily basis.

Thank you for your time and attention and I would be happy to answer any questions that you may have.

Senator BENNETT. Thank you very much.

Mr. BOST. Thank you, Mr. Chairman.

[The statements follow:]

PREPARED STATEMENT OF ERIC M. BOST

Thank you, Mr. Chairman, and members of the Subcommittee for allowing me this opportunity to present our budget request for fiscal year 2004.

With your permission I would also like to introduce three members of the FNCS team accompanying me today. Suzanne Biermann, the Deputy Under Secretary for Food, Nutrition, and Consumer Services, Roberto Salazar, Administrator of the Food and Nutrition Service, and Dr. Eric Hentges, the Executive Director of the Center for Nutrition Policy and Promotion.

The President's Budget for fiscal year 2004 requests $44.2 billion in new budget authority, reflecting the Administration's commitment to the nutrition safety net that protects the Nation's children and low-income households from hunger and malnutrition and motivates them to make smart food choices and engage in physical activity to promote their health and well-being. The purposes to which we will put this substantial commitment are clearly defined and tightly focused on the achievement of three critical outcomes. First, we intend to do our part to address both within nutrition assistance programs and, through the Center on Nutrition and Policy Promotion, in the general population, the growing public health threat of obesity. Secondly, we seek not just to maintain, but to improve the access of eligible persons to our programs. Finally, we will continue our pursuit of improved performance and program integrity.

COMBATING OBESITY

The choices that consumers make related to their diet and physical activity have a major impact on their health. Poor diets and sedentary lifestyles cost this Nation dearly in medical costs, in lost productivity, and most sadly, in the premature deaths of over 300,000 citizens annually. We are committed to do our part, within the larger framework of President Bush's HealthierUS initiative, to combat this epidemic. Nutrition assistance programs play a critical role in fostering good health and preventing diet-related health problems by ensuring access to nutritious food to those who need it, and by promoting better diets and physical activity through nutrition education to program participants.

This budget request reflects this priority. We have requested $25 million for peer counseling to enhance our breastfeeding promotion efforts in the WIC Program and demonstration projects to evaluate how WIC can be used to combat obesity among our children. We are also seeking to expand our very successful Eat Smart. Play Hard. campaign to other FNS programs beginning with WIC and Food Stamps. Finally, we are seeking resources to develop an integrated, family-oriented approach to nutrition education that cuts across all our programs. These activities allow the Department to partner with other Federal agencies as we work across Departments to meet the President's challenges for a HealthierUS.

The need to improve diets to fight overweight and obesity extends to the general public as well. Our request also supports USDA's Center for Nutrition Policy and Promotion, which works with the Department of Health and Human Services and other agencies to promote good nutrition to all Americans. Within this budget request are resources to update and promote the Food Guide Pyramid, one of the foremost nutrition education tools in the Nation, to develop the next revision of the Dietary Guidelines for Americans and to support obesity prevention efforts for the general public as part of the President's HealthierUS initiative.

ENSURING PROGRAM ACCESS

Ensuring access to the nutrition assistance programs is a top priority of this Administration. Our commitment is to ensure that every eligible person has access to the benefits they need. The Department's new Strategic Plan includes strategies to improve access to a number of underutilized programs and to pursue education and outreach efforts to make eligible people aware of nutrition assistance. At the most basic level, we have consistently designed the budget to ensure that the Programs are adequately funded to meet the demand for services. This includes proposing

record funding levels over the past 2 years for the WIC Program and reinforcing that funding with a contingency fund. A similar reserve in the Food Stamp Program prevented any disruption in the flow of benefits to 19.8 million food stamp recipients last September when program needs exceeded the base appropriation. We are requesting the continuation of the Food Stamp reserve in fiscal year 2004.

As is clear in this budget request, we are committed to access as a key principle in our effort to improve the design and administration of the nutrition assistance programs.

STRENGTHENING INTEGRITY AND PROGRAM MANAGEMENT

We are ever conscious of our responsibility to protect the American taxpayer's investment in the nutrition safety net. To maintain the public's trust, we are committed to the sound stewardship of those resources. This budget funds efforts to improve program management and integrity both at the Federal level and by our State partners. Also included is funding to maintain our level of effort to reduce errors in the Food Stamp Program. Our payment accuracy rate for fiscal year 2001, the most recent year with data available, was 91.34 percent. This is the best payment accuracy rate that the Food Stamp Program has ever experienced. We will continue our efforts and work with State partners to reduce errors even further.

We are proposing targeted investment in new efforts to enhance program management and stewardship. For example, in the WIC Program, the President's request provides $30 million to support the enhancement and modernization of the State-level information systems that have become so important to proper management of the Program. This kind of improvement is essential to strengthening program management, maintaining a high level of program integrity and, to the extent possible, preventing errors and other problems before they occur.

In the remainder of my remarks, I would like to highlight a few key components of our request.

FOOD STAMP PROGRAM

The President's budget requests $27.7 billion for the Food Stamp Program, enough to serve an average of 21.6 million people each month. The request includes sufficient funds to support the changes enacted in last year's Farm Bill including the restoration of eligibility to many legal immigrants. Included in this amount, we also propose to continue the $2 billion benefit reserve. The importance of this reserve is especially critical in fiscal year 2004. While we anticipate a return to strong economic growth, predicting the turning point of program participation is challenging. The proposed contingency reserve will ensure the availability of benefits for eligible households should participation or food costs exceed current estimates.

CHILD NUTRITION PROGRAMS

The budget requests $11.4 billion for the Child Nutrition Programs, which provide millions of nutritious meals to children in schools and in child care settings every day. This level of funding will support an increase in daily School Lunch Program participation from the current 28 million children to over 29 million children. This funding request also supports an increase in daily School Breakfast Program participation from the current 8 million to over 9 million children. Requested increases in these programs also reflect rising school enrollment, increases in payment rates to cover inflation, and higher levels of meal service among children in the free and reduced price categories.

WIC

The President's budget includes $4.8 billion for the Special Supplemental Nutrition Program for Women, Infants and Children, the WIC Program. This year's request will allow local communities to provide food, nutrition education, and a link to health care to a monthly average of 7.8 million needy women, infants and children during fiscal year 2004. The request provides for a contingency fund of $150 million. These resources can be used as needed if food costs or participation exceed current estimates.

COMMODITY SUPPLEMENTAL FOOD PROGRAM (CSFP)

The budget requests $95.0 million for CSFP, which serves elderly people and women with infants and young children. The funds requested plus anticipated carryover from fiscal year 2003, surplus donations and commodities currently in inventory will be sufficient to maintain this program in States that currently participate and those that join the program in fiscal year 2003.

THE EMERGENCY FOOD ASSISTANCE PROGRAM (TEFAP)

As provided for in the Farm Bill, the budget requests $140 million for food in this important program. Our request for States' storage and distribution costs, a critical form of support for our Nation's food banks, is $50 million. Secretary Veneman has committed to ensuring the continuing flow of surplus commodities to TEFAP. Such donations significantly increase the amount of commodities that are available to the food bank community from Federal sources.

NUTRITION PROGRAMS ADMINISTRATION (NPA)

We are requesting $144.8 million in this account, which includes an increase of $8 million and 13 staff years in our administrative budget. This increase supports the child nutrition program integrity initiative described earlier, as well as a number of initiatives under the Center for Nutrition Policy and Promotion designed to combat obesity and improve the dietary quality of all Americans. Our total request for Federal administrative resources represents only about 0.5 percent of the program resources for which we have responsibility and sustains the program management and support activities of our roughly 1,700 employees nationwide. I believe that we need these modest increases in funding in order to maintain accountability for our $44 billion portfolio and to assist States to effectively manage the programs and provide access to all eligible people.

CHILD NUTRITION ACT REAUTHORIZATION

As I stated in my testimony before this Committee last year, I personally feel very fortunate to have the opportunity to participate in the reauthorization of important programs such as the school breakfast and lunch programs, the WIC Program, and the summer feeding program. Congress and the Administration face a range of important challenges in this reauthorization cycle. Among these is combating obesity among our youth, ensuring access to our programs, improving the nutritional content of meals, and enhancing program integrity and administration.

Toward meeting these challenges, the Administration has established a set of principles to guide the reauthorization process. Key among these are:

—Ensuring that all eligible children have access to program benefits—including streamlining the administration of programs to minimize burdens and increase meal reimbursements to provide support for quality program meals.

—Supporting healthy school environments—providing financial incentives to schools that promote good nutrition, including serving meals that meet the dietary guidelines, offer healthy-choice alternatives, and provide nutrition education.

—Strengthening program integrity—the budget also makes clear that if there are any savings resulting from integrity initiatives these funds would be reinvested into the Program to ensure the best outcomes for those in need.

In sum, our request sets the right priorities to ensure access to the Federal nutrition assistance programs for the children and low-income people who need them, while maintaining and improving their integrity and supporting our efforts to address the growing public health threat of obesity. Thank you for your attention; I would be happy to answer any questions you may have.

PREPARED STATEMENT OF ROBERTO SALAZAR, ADMINISTRATOR, FOOD AND NUTRITION SERVICE

Thank you, Mr. Chairman, and members of the Subcommittee for allowing me this opportunity to present the budget request for the Food and Nutrition Service for fiscal year 2004.

The mission of the Food and Nutrition Service is to increase food security and reduce hunger together with cooperating organizations by providing children and low-income people access to food and nutrition education in a manner that inspires public confidence and supports American agriculture. We are requesting a total of $44.2 billion to fulfill this mission through the Federal nutrition assistance programs.

As the Under Secretary noted, the request for FNCS focuses on the accomplishment of three critical outcomes:

—To address the emerging epidemic of obesity, especially among America's youth, by improving our programs' ability to support healthy eating and physical activity, including better integration of nutrition education into Federal nutrition assistance.

—To improve access to these programs, to ensure that all those eligible are able to participate.

—To enhance performance and integrity in the programs, to strengthen their operation and maximize their ability to serve eligible children and low-income people while safeguarding the taxpayer's investment in nutrition assistance. I'd like to offer you some details from our request that provide the link between the investments we intend to make and these important goals.

COMBATING OBESITY

The budget request includes funding to promote healthy eating and physical activity to prevent nutrition related illnesses in America. These are core objectives of the nutrition assistance programs, as they represent a unique opportunity to reach populations that experience a disproportionate share of diet-related problems and risk factors including overweight and obesity.

FNS is working on a number of fronts to harness the power of the nutrition assistance programs to combat obesity, such as:

—As part of the President's HealthierUS initiative, we are pursuing a vigorous nutrition promotion campaign, Eat Smart. Play Hard. The campaign is designed to motivate healthy eating and more physical activity;

—We are working to improve the nutritional content of school meals, food packages and other benefits to ensure that they continue to contribute to a healthful diet;

—We are expanding and improving program-based nutrition education, such as Team Nutrition, and other nutrition services to improve healthy eating skills of participants;

—We have made significant improvements in the nutritional quality of school meals, lowering the percentage of calories from fat and saturated fat as well as reducing levels of sodium and cholesterol; and

—We are enhancing our support of breastfeeding, a proven strategy to reduce the early incidence of obesity, through peer counseling and exploring other ways in which WIC can assist in the battle against childhood obesity.

In addition, FNS and the Center on Nutrition Policy and Promotion are working in partnership with other USDA agencies, the National Cancer Institute and the Centers for Disease Control and Prevention, to increase the consumption of fruits and vegetables to 5 to 9 servings per day for a healthier eating pattern.

ENSURING PROGRAM ACCESS

The budget request includes funding to support initiatives to ensure access for low-income individuals who are eligible to participate in our programs. While the Food Stamp Program reaches tens of millions of low-income Americans every month, many others who are eligible for benefits, including many seniors and the working poor, do not participate. To better reach these eligible nonparticipants, we have launched a major new public information campaign, "Food Stamps Make America Stronger", awarded grants to 33 local and state organizations over the last 2 years to assist the working poor, elderly, legal immigrants, and other low-income families and individuals, and are prepared to award another $5 million in grants this year to help States improve the food stamp application process as authorized by the Farm Bill.

To meet our commitment to improve access for all who are eligible, we must work closely with our program partners—individuals and organizations in communities across America who deliver the nutrition assistance programs, and work to make them accessible and effective. Faith-based organizations have long played an important role in raising community awareness about program services, assisting individuals who apply for benefits, and delivering benefits. President Bush has made working with the faith-based community an Administration priority, and we intend to continue efforts to reach out to that community in fiscal year 2004.

STRENGTHENING INTEGRITY AND PROGRAM MANAGEMENT

We are requesting additional funding in the President's budget to strengthen integrity and program management both at the Federal and State levels. In the Food Stamp Program, FNS administers a quality control system that encourages payment accuracy by establishing fiscal liabilities and incentives based on State performance in benefit determinations. In fiscal year 2001, the rate of overissuance was 6.47 percent ($1 billion) and the rate of underissuance was 2.19 percent ($340 million) for a combined payment error rate of 8.66 percent, the lowest in the history of the program. We expect performance to have improved in fiscal year 2002. But continued vigilance will be needed to sustain and to continue to improve on this record. One factor as we continue our commitment to performance is that food stamp caseloads

in virtually every State are rising, while at the same time many States face significant budget deficits.

Another focus of our integrity efforts is improving the accuracy of certifications for free and reduced price school meals. As you know, FNS has been analyzing this problem for a number of years; while we do not have a measure of its full extent, the indications are clear that the problem is real, and may have worsened in recent years.

Inaccurate certifications represent a risk that free and reduced price meals could be provided to ineligible participants. Furthermore, certifications are used to distribute billions in Federal, State, and local education aid; errors can undermine targeting of aid to those most in need.

USDA has been working for a number of years to collect additional information to learn more about the problem, and to identify potential solutions. Current efforts include pilot-tests of alternative free and reduced-price eligibility determination systems, administrative reviews of the current verification process in a number of school districts, and a study to assess the eligibility status of families selected for income verification.

The President's Budget proposes to improve the accuracy of eligibility decisions and to reinvest any savings from improved payment accuracy in ways that strengthen the program, ensure the access of all eligible children and improve the nutritional quality of meals. We have had a continuing dialogue with the Congress, the school food service community and program advocates trying to find a solution to this problem that does not deter eligible children from participation in the program and does not impose undue burdens on local program administrations. This will be an issue in the upcoming reauthorization of the Child Nutrition Programs. In the meantime, we will soon be issuing a final regulation that will require local agencies to report certification verification results to State agencies. The States, in turn, will use this information and meal data to target technical assistance activities to school food authorities with the highest levels of verification errors.

FNS is addressing Child and Adult Care Food Program (CACFP) management weaknesses identified by Federal and State reviews and in OIG audits. A regulatory proposal published in September 2000, proposed changes to State and local monitoring and training requirements. An interim rule that implemented statutory changes to the CACFP was published in June 2002, and training on the rule was provided to State and Federal CACFP staff during the fall of 2002. A second interim rule will be published during the summer of 2003 to implement the remaining provisions.

Now, I would like to review some of the components of our request that relate to these outcomes under each program area.

FOOD STAMP PROGRAM

We are requesting $27.7 billion for the Food Stamp Program, including a $2 billion benefit reserve as appropriated in fiscal year 2003. This proposed reserve would be available for eligible households in case participation exceeds current estimates. Participation is estimated to increase by 871,000 to a level of 21.6 million participants in fiscal year 2004. This level of funding will also support approximately 200,000 new recipients covered under the 2002 Farm Bill changes to eligibility requirements for legal immigrants and other individuals.

CHILD NUTRITION PROGRAMS

For these programs, we are requesting a total of $11.4 billion. The budget request will support the daily participation of over 29 million children in the School Lunch Program and over 9 million children a day in the School Breakfast Program. The cost of snacks served under the after school National School Lunch Program is also included in this request. We estimated 41 million meals above the fiscal year 2003 estimate in the Child and Adult Care Food Program. The request also includes additional funding to support increases in school enrollment, increases in payment rates to cover inflation, a higher proportion of meals served to children in the free and reduced price categories and to support efforts to improve integrity.

SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC)

The President's request of $4.8 billion will enable us to provide benefits to a monthly average of 7.8 million needy women, infants and children during fiscal year 2004. This is a record-level request that shows the Administration's commitment to this effective and critical program for mothers and their young children. We believe this funding will provide benefits and services to all who are eligible and wish to

participate. In October of 2002, WIC participation reached a record high of over 7.66 million participants. Since then, participation has fallen, consistent with historical trends toward lower participation in the winter months than during the rest of the year. We expect program demand to grow throughout the spring and summer. This request supports a $150 million contingency fund to allow WIC to serve all eligible persons seeking benefits should funding be insufficient for any reason.

THE EMERGENCY FOOD ASSISTANCE PROGRAM (TEFAP)

We are requesting $140 million, as provided for in the Farm Bill, to purchase commodities for this program. Our funding of States and local agencies costs associated with the distribution of commodities is a vitally important part of our support of the TEFAP community and we are requesting $50 million for this purpose. As Under Secretary Bost has noted in his testimony, Secretary Veneman has committed the Department to a continuing flow of surplus commodities to TEFAP at levels comparable to recent years. These surplus commodities are an essential resource to the food banks and significantly enhance their ability to serve the needy in their communities.

NUTRITION PROGRAMS ADMINISTRATION

Our Nutrition Programs Administration (NPA) request for fiscal year 2004 is $144.8 million, an increase of approximately $8 million over the fiscal year 2003 enacted level. We are requesting approximately $2.9 million for pay cost increases and $1 million to fund 13 additional staff years to enhance program integrity in the Child Nutrition Programs. The request also includes an increase of $4.0 million to enable us to expand our initiatives to combat obesity, reduce diet-related disease among all Americans, and support the President's HealthierUS intiative. The Center for Nutrition Policy and Promotion, also included in this budget request, will continue the process of updating the Food Guide Pyramid, one of the Nation's most important nutrition education tools; updating the Interactive Healthy Eating Index; working jointly with the Department of Health and Human Services on the updated Dietary Guidelines for Americans; and begin development of an obesity prevention campaign. As noted by Under Secretary Bost, FNS will be expanding its very effective Eat Smart. Play Hard. campaign to WIC, Food Stamp and possibly other nutrition assistance programs. The agency will also initiate development of family-oriented, nutrition education messages that are useful and relevant across the full range of our programs.

Thank you for the opportunity to present this written testimony.

Senator BENNETT. Dr. Murano.

STATEMENT OF ELSA MURANO

Dr. MURANO. Good morning, Mr. Chairman, members of the subcommittee. We have the safest food supply in the world, and I say that with all confidence because I know when one looks at the rates of illness per 100,000 people in a population in any country, we do have the lowest. So I am very proud to say that unequivocally here.

The safety of our food supply, as you have all stated, is one of the most important issues that we face. The public expects its food to be safe, and as a public health official, I take very seriously my job to meet that expectation. I came to Washington to do that job.

Providing consumers with a safe food supply is an ongoing challenge, however. On the one hand, we must rapidly respond to day-to-day events, such as product recalls, outbreaks of foodborne illness, and reports of potential food safety hazards, like we have this week. On the other hand, we must have a solid food safety infrastructure, strong policies in place, and the appropriate expertise available to handle these day-to-day events. These cannot be developed in days, weeks, or even months. They require long-term efforts and resources. In other words, it is not enough to say that we

are doing everything we can to protect the public health. We must be able to back up such statements with concrete actions.

So let me use BSE as an example. Our efforts to guard against BSE in the United States began in 1989, as you know, when FSIS, in cooperation with other government agencies that are appearing before you today, APHIS and FDA, took a series of preventive actions to protect against this animal disease, which can potentially have human health implications. Mr. Hawks, I am sure, will mention some of these, and certainly Mr. Johnson has mentioned the ban on the use of ruminant materials in animal feed, and also the ban on the import of animals from countries that are known to have BSE.

In addition, FSIS is finalizing a rule to ban the use of air-injected stunning and has also implemented a rigorous process verification program of beef that is produced by advanced meat recovery systems to ensure that high-risk materials are absent from our beef supply.

So in the same manner, while outbreaks of foodborne illness continue to occur, we have made significant improvements to our food safety programs to minimize their occurrence and their effects. For example, we are now using epidemiological evidence to link cases of foodborne illness to specific products that we regulate. This means that an outbreak can be traced to its source more quickly, potentially reducing the number of illnesses.

In March of 2003, the Centers for Disease Control and Prevention reported that the rate of foodborne illness across the board is down 16 percent over the last few years, and this is good news, indeed.

The behind-the-scenes work that FSIS carries out is detailed in my statement for the record, but let me just point out a few highlights of our accomplishments this last year and a half. We have introduced more highly skilled scientific experts into our workforce, including consumer safety officers and Public Health Service commissioned officers, and we have taken the first steps towards revitalizing our training and education programs to better prepare our inspectors, and our employees, to function in a public health agency, which is what FSIS is.

Recognizing that *E. coli* O157:H7 is more prevalent than previously thought, we directed establishments to reassess their HACCP plans for this pathogen, and we are verifying that these reassessments have taken place.

We completed our risk assessment on *Listeria monocytogenes* and issued a directive stating that FSIS would intensify its testing program for this pathogen in instances where plants either don't have adequate controls or have these controls but don't share their data with us.

To improve the security of the food supply, we hired 20 new import surveillance officers. We assessed vulnerabilities from farm to table, developed and distributed guidelines to industry on plant security, and have done many, many other functions that I will be happy to visit with you about.

We are carrying out our reorganization of the Food Safety and Inspection Service to better prepare the agency to meet its public health goals. This includes a new internal review office. It is our

own quality control office, if you will, so that we don't wait for OIG reports or GAO reports to tell us where our vulnerabilities or weaknesses may be.

And last but not least, to take our food safety message directly to the people who need it, we are sending our new USDA Food Safety Mobile to strategic locations throughout the country.

PREPARED STATEMENTS

Mr. Chairman, in the interest of time, I will not go on and tell you the specifics of our budget request. I think you have them before you. So I will close my comments and pledge to you that we continue to do everything that we can to show the public that they do have a safe food supply and that they can rely on that fact, and so with that, I will yield to Mr. Hawks.

Senator BENNETT. Thank you very much.

[The statements follow:]

PREPARED STATEMENT OF DR. ELSA MURANO

Mr. Chairman and Members of the Subcommittee, I am pleased to appear before you today to discuss the fiscal year 2004 budget for food safety within the Department of Agriculture (USDA). I am Dr. Elsa Murano, Under Secretary for Food Safety. With me today are Dr. Merle D. Pierson, Deputy Under Secretary for Food Safety; Dr. Garry McKee, Administrator of the Food Safety and Inspection Service (FSIS); and Ms. Linda Swacina, Associate Administrator.

The safety of our food supply is one of the most important issues we face not only at USDA, but as a nation: there is nothing more personal or vital to all of us than the food we provide to our families. President Bush's budget for fiscal year 2004 includes record-level support for USDA's food safety programs and their basic mission of providing continuous food safety inspection in each meat, poultry, and egg products establishment in the country. The additional $42 million requested for FSIS will be used to fund several important initiatives that I would like to review with you in a moment.

Before I cover those initiatives that will be implemented from the additional $42 million requested for FSIS, I want to discuss what has happened in the past year, our progress on the five goals to improve food safety, our efforts to improve international food safety, and our plans for the future.

What Has Happened During the Past Year

We have the best food production and processing systems in the world, providing consumers with the most abundant and safest food supply. However, last year was a testament that maintaining the safety of our food is an ongoing challenge. We faced two major recalls, one caused by Listeria monocytogenes, another caused by E. coli O157:H7.

We take our public health mission very seriously, and we will do what is necessary to accomplish that mission. According to the Centers for Disease Control and Prevention (CDC), over the past decade, there has been a major Listeriosis outbreak associated with ready-to-eat products in the United States every 2 to 4 years. In addition, E. coli O157:H7 outbreaks due to consumption of undercooked hamburgers are almost an annual occurrence.

Despite these challenges, we have made significant improvements to our food safety program. We believe that the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) rule in 1996 has made food safer. In May 2002, the CDC reported that the rate of foodborne illnesses, across the board, is down 21 percent.

We have also made great strides in improving the technical and scientific knowledge of our inspection force. With the introduction of the Consumer Safety Officer corps we have introduced highly-skilled, scientific experts into the field to reinforce our veterinarians and front-line inspectors. We are driven by the fact that the enormity of our responsibility cries out for a science-based system and we continue to incorporate state-of-the-art science into the inspection process at every opportunity.

Those strides are great, but we need to address how we are going to protect public health further. Throughout my career as a researcher, I have become keenly aware of the importance of sound scientific studies and how these can help provide us with

the critical information and practical application of science we need to make decisions that will truly reduce the risk of foodborne illness. I have also observed the need for a proactive approach, one that does not simply react to food safety crises, but rather anticipates risks and prepares to mitigate their potential for harm. We need to improve across the board in everything we do including our public education campaigns; laboratory testing; inspector training; and in-plant inspection.

The Five Goals To Improve Food Safety

I want to review some of the achievements we have made in improving food safety. Last year when I testified before this Committee, I outlined to you five goals that I intended to pursue in the coming year to ensure that we are proactive in protecting public health. We have pursued these goals with vigor, and we continue to do so. I am proud to report that much has been accomplished over the last year in our pursuit of these goals to ensure the safety of the nation's food supply.

Before I cover our accomplishments under each of the five goals, I would like to review them quickly. They are:

—Ensure that policy decisions are based on science;
—Improve the management and effectiveness of FSIS programs;
—Improve coordination of food safety activities with other public health agencies;
—Protect meat, poultry, and egg products against intentional harm; and
—Enhance public education efforts.

Goal #1: Ensure that Policy Decisions are Based on Science

My first goal is to ensure that policy decisions are based on science. As I mentioned earlier, employing science is the only way we are going to break the cycle of foodborne illness. My background as a researcher in food safety has shown me the importance of utilizing science in formulating regulatory policy.

If we take a look at two of the pathogens that have recently been on our radar screen—E. coli O157:H7 and Listeria monocytogenes—then we see that these organisms are representative of the universe of microbial hazards that pose the biggest threat to the safety of our food supply.

The first one, E. coli O157:H7, comes to us through live animals that may have the organism on their bodies or in their intestinal tracts. Thus, its control hinges on minimizing its presence in the intestinal tract of food animals and in preventing its contents from reaching raw products derived from these animals.

The second pathogen, Listeria monocytogenes, is an environmental pathogen carried by personnel, equipment and water, which can spread the pathogen when they contact food. Thus, its control hinges on finding where it might be harbored in the environment of the food processing plant and eliminating it so as to prevent contamination of food-contact surfaces.

Risk assessments help give us a picture of the pervasiveness of these organisms. Risk assessments are scientifically-based processes of estimating the likelihood of exposure to a hazard and the resulting public health impact. They provide a solid foundation from which we base policies on science.

The benefits of using them can be seen in our initiatives on E. coli O157:H7 and Listeria monocytogenes last year. We learned from our risk assessment on E. coli O157:H7 that the pathogen was not the proverbial needle in a haystack we once believed. On the contrary, it was much more prevalent than previously thought, which meant that we had to take a hard, new look at our strategies to address its occurrence. Not all establishments were implementing HACCP systems that were effective for controlling E. coli O157:H7. Others were not correctly validating the interventions used to control the pathogen. We realized that simply focusing on grinding operations was not effective; therefore, in order to be efficient, we also needed to focus on the production process, the slaughter process, and trimmings as contributors to the problem.

In November, we issued a directive to our inspectors to make sure that establishments producing ready-to-eat meat and poultry products are preventing Listeria monocytogenes contamination. This directive was absolutely necessary given the gravity of the Northeastern Listeriosis outbreak in the fall. Furthermore, we recently completed a draft risk assessment on Listeria, which evaluates the factors that may contribute to the overall risk to public health. The information developed during the risk assessment process is critical to exploring a variety of risk management scenarios and we plan to examine different combinations of testing and intervention that present possibilities for future policy making. We used the risk assessment as we worked on a final rule to reduce Listeria in processing plants producing ready-to-eat meat and poultry products. We have moved as rapidly as we can to develop this final rule while using sound science as the basis and expect to publish it in the Federal Register soon.

In a perfect world, risk assessments would be completed before risk management strategies are developed. But in the real world, we may not have this luxury. We must design risk management strategies based on what we know today and improve them as more information becomes available.

Another way we have based policy decisions on science has been through a series of scientific symposia we hosted on specific issues ranging from applied epidemiology, pathogen reduction, and Listeria. These symposia offer an opportunity to hear from experts in academia and government and allow for a dialogue on how we can improve the scientific basis for our food safety programs and policies.

Most recently, on April 29, FSIS sponsored the Second Scientific Symposium on Applied Epidemiology. This meeting was the second in a series of meetings aimed at aiding FSIS in developing a framework for how the agency will conduct public health investigations and integrate the scientific principles of applied epidemiology into its food safety activities. The successful meeting served as an open forum to discuss the agency's approach to investigations of foodborne illnesses associated with meat, poultry, and egg products and the progress the agency has made using epidemiology as a basis for regulatory decision making.

Goal #2: Improve the Management and Effectiveness of FSIS Programs

The second goal I'd like to discuss is improving the management and effectiveness of FSIS programs. In order to fulfill this goal, we needed to select a leader to head FSIS through one of its most profound transformations toward a public health mission.

I was looking for certain traits in this individual. These included a scientific background, strong management skills, a sense of accountability to everybody in the organization, and most important, a proven track record of public health service and commitment. This person would also have to be a motivator.

I am truly proud to say that I have found all these traits in the selection of Dr. Garry McKee, who started with FSIS on September 1, 2002. In this very short time he has made a very positive impression on agency employees and constituents alike. Dr. McKee is a committed public health professional with over 30 years of public health experience and a proven leader in managing public health programs and personnel. He brings unparalleled enthusiasm, determination, and commitment toward public health to the helm of FSIS and I certainly believe that his tenure will be regarded in the future as a significant turning point in FSIS' long history.

The selection of an Administrator was critical, but so too was the reorganization of the agency that began last year. This reorganization will prepare the agency to better meet its public health and food safety goals. The purpose for this reorganization is to increase accountability, enhance communication, and improve overall efficiency.

This reorganization will also ensure that the principles of public health and food safety cut across the entire spectrum of FSIS' work. We have added four assistant administrators for Food Security; Program Evaluation, Enforcement, and Review; Communications, Outreach and External Review; and International Coordination to strengthen the working relationship between our various offices.

With Dr. McKee's leadership, we are already seeing increased accountability for all FSIS employees; improved communication and cooperation that flows smoothly and quickly throughout the organization, as well as laterally across all divisions and to outside agencies; and increased efficiency in the agency's programs. As a public health agency, lives depend on our programs and operations to work as a well-oiled machine.

Another key to enhancing the consistency and effectiveness of FSIS inspection entails a revitalization of training and education programs conducted by the agency to instruct our workforce on HACCP sanitation procedures and other regulatory measures. The agency is in the process of redesigning current training programs to enhance distance learning opportunities and improve hands-on training methods. We realize that our workforce is the backbone of FSIS. We rely on our field employees to be in every meat, poultry, and egg products plant, ensuring that the plants are producing products that are safe, wholesome, and accurately labeled. Our frontline employees are responsible for making the critical determination that products are not adulterated and are safe to eat. They are also responsible for identifying and preventing intentional threats to the food supply. As a result, we believe that it is absolutely necessary to have a scientifically- and technically-trained workforce that is dedicated to ensuring a safe supply of meat, poultry, and egg products. FSIS is refocusing and retooling its training efforts because a well-trained and competent workforce is a key element to the success of our critical food safety and public health mission.

We have also strengthened our workforce's ability to enforce the HMSA. All of the over 7,600 FSIS inspection personnel are expected to enforce the Humane Methods of Slaughter Act (HMSA) and take enforcement action for humane handling and slaughter violations. FSIS has inspection personnel trained in humane methods of handling and slaughter in all of the nearly 900 federally inspected U.S. livestock slaughter establishments. In addition to their food safety-related inspection responsibilities, these veterinarians and inspectors are charged with observing the methods by which livestock are slaughtered. FSIS inspectors and veterinarians, who provide continuous inspection in every slaughter facility, are required to take immediate enforcement action when a violation is observed. FSIS personnel who fail to enforce the HMSA are considered negligent in their duties and are subject to disciplinary action. FSIS has taken, and will continue to take, enforcement actions against plants that do not follow humane handling requirements.

In addition, FSIS used funding allocated in the fiscal year 2001 Supplemental bill to hire 17 veterinarians to serve as District Veterinary Medical Specialists (DVMS) in each of the agency's districts. The DVMS reported for duty on December 30, 2001. The DVMS have been trained in all aspects related to humane handling and slaughter, including antemortem inspection, humane handling regulations, the HMSA, stunning methodologies, assessing consciousness, enforcement procedures related to humane handling, and workplace violence. They also serve as the program coordinators for all humane handling issues within their districts and are providing training to newly hired in-plant Veterinary Medical Officers on the agency's humane handling and slaughter responsibilities.

In addition to our reorganization and training efforts, FSIS is continuing the pilot inspection system, known as the HACCP-based Inspection Models Project, or HIMP, to address the online slaughter process. I view HIMP as a means of increasing the effectiveness of our inspection force and the efficiency of our food safety systems, while in no way compromising food safety or our process control system.

Under HIMP, one FSIS inspector inspects each carcass at the end of the line, while other FSIS inspectors are given the freedom to move throughout the facility and the slaughter line to ensure that the plant's critical control points in its food safety system are effectively preventing and stopping pathogens and other food safety hazards, resulting in more intense and effective inspection and verification activities. In June 2002, FSIS made data from the National Alliance for Food Safety (NAFS) available comparing HIMP and traditional inspection, which indicate that HIMP is at least equal to the traditional inspection system. In September 2002, an independent review of the HIMP data concluded that "the HIMP system compared favorably to the traditional system of inspection." FSIS is encouraged by this data and we intend to use these results to further modernize our inspection system to most effectively prevent and control food safety hazards.

Goal #3: Improve Coordination of Food Safety Activities with Other Public Health Agencies

We have also made progress with the third goal to improve coordination of food safety activities with other public health agencies. I am a strong believer that by working together, all the agencies with public health responsibilities can best utilize our resources to ensure a safe food supply.

An example of our progress in this area was an unprecedented investigation that we coordinated with the CDC and other State and local public health agencies on the Northeastern listeriosis outbreak last year. FSIS dispatched seven teams beginning in early September to affected Northeastern States and used information provided by CDC to test products and visit plants that were suspected of being linked to the outbreak. More than 400 tests were taken in the course of the investigation. When we first suspected that a turkey product caused the outbreak, we took the necessary steps to identify the plant. When the plant was identified, FSIS immediately conducted a recall and sent a team of specialists to the establishment to identify and help correct any problems in the plant. We spent an enormous amount of time and resources investigating this outbreak including creating a team of more than 50 laboratory scientists, regional epidemiologists, consumer safety officers, compliance officers, field personnel and headquarters management to work closely with CDC and State and local public health officials to locate the source.

This effort was enhanced by our cadre of FSIS epidemiologists, many of which are Public Health Service (PHS) Commissioned Officers. We believe so strongly in the significant role the PHS can play in helping FSIS carry out its food safety mission that on April 17, 2003, we signed a Memorandum of Agreement (MOA) with the U.S. Department of Health and Human Services' PHS Commissioned Corps, to expand the role and number of PHS Officers detailed to FSIS. The addition of these

PHS Commissioned Officers will enhance FSIS' capabilities for rapid response during heightened security alerts or an actual threat to food security.

Another example is our very close working relationship with the Food and Drug Administration Commissioner, Dr. Mark McClellan. We have established regular meetings with Dr. McClellan's office to increase our interaction on issues of mutual concern and to discuss policy positions of common interest.

States are also an integral part of the U.S. food safety system. We are working to update and strengthen the Federal State review process through a number of means. FSIS is working diligently to address the congressional mandate in the 2002 Farm Bill requiring us to carry out a comprehensive review of State Meat and Poultry Inspection programs. The agency has also published voluntary security guidelines to help State-inspected plants that produce meat, poultry, and egg products in identifying ways to strengthen their security plans to protect against acts of bioterrorism.

Another area in which we are making major strides is our cooperation with States through the sharing of recall information. In July 2002, FSIS published a final rule allowing the agency to share a firm's distribution list with State and Federal agencies in the event of a meat or poultry recall through a Memorandum of Understanding. This change allows for better communication and coordination between FSIS and the numerous State and Federal agencies that are involved in product recalls.

Goal #4: Protect Meat, Poultry, and Egg Products Against Intentional Harm

Close coordination with other public health agencies is also very important in protecting the food supply against intentional harm, which leads me to the fourth goal. Since the attacks on September 11, 2001, FSIS has strengthened coordination and preparation efforts to prevent, detect, and respond to food-related emergencies resulting from acts of terrorism, and ensure the safety of meat, poultry, and egg products that come to us from other countries. With a strong food safety infrastructure already in place, FSIS has been able to focus on strengthening existing programs and improving lines of communication, both internally and externally.

We have implemented several measures to protect the public from contaminated product entering the United States from abroad. In addition to reinspecting imported product, FSIS continually assesses foreign establishments to make sure their sanitation and inspection procedures are equivalent to those in the United States.

To augment the efforts of traditional FSIS import inspectors, FSIS has also added 20 new import surveillance liaison inspectors who are on duty at ports-of-entry. Where traditional USDA import inspectors examine each shipment and conduct reinspection activities, these new import surveillance liaison inspectors conduct a broader range of surveillance activities at each import facility and serve as liaisons to improve coordination with other agencies concerned with the safety of imported food products, such as the Department of Homeland Security.

Furthermore, FSIS introduced the new Automated Import Information System (AIIS), which focuses on a foreign country's inspection system as a whole, rather than on individual plants. This system, using statistics, chooses imports for reinspection based on the annual volume of shipments from the exporting country. Previously, for all countries except Canada, reinspection was randomly assigned based on an establishment's compliance history. The new system is user-friendly and allows inspectors at all ports-of-entry to share data. It also allows managers to have easier access to inspection reports. The new AIIS also provides better tracking of shipments once they enter the United States, and FSIS' next step is to integrate the system with USDA's Animal and Plant Health Inspection Service (APHIS) and the U.S. Customs systems to further strengthen the food safety system against intentional attacks.

Besides our initiatives to screen imported products, we have conducted a vulnerability assessment to be used as a tool for determining the most vulnerable products, likely agents, and potential sites for deliberate adulteration of domestically produced meat, poultry, and egg products. The assessment was conducted using a farm-to-table approach based on current knowledge of the industrial processes used in the production of these products and the potential biological and chemical agents that could be introduced. The assessment was concluded in June 2002 and the information obtained is being used to develop risk management strategies, including ensuring that our laboratories are equipped with the methods and personnel necessary for detecting agents of concern.

We are also developing a vulnerability assessment of the import system to identify points in the production of imported products where biological, chemical, and radiological contaminants could be intentionally added to foods being brought into the United States. FSIS used the risk analysis framework to conduct a relative risk

ranking to be used to allocate resources to monitor U.S. ports-of-entry for those food commodities that pose the greatest risk, examine different intervention strategies for preventing or reducing risks, develop biohazard identification protocols, and target training of personnel and develop educational campaigns to increase awareness. This assessment is expected to be completed in September 2003.

We have taken preparation for food safety emergencies to a higher level with simulation exercises. Earlier this year, we conducted an exercise known as "Crimson Winter" to familiarize our managers and staff with the operating environment that would exist during an outbreak of foodborne disease—the cause being intentional or unintentional. This exercise was very constructive for our senior management, emergency response team, our partners in the Food Threat Preparedness Network, and other relevant Federal and State agencies.

Goal #5: Enhance Public Education Efforts

Finally, goal number five is to engage in proactive education programs. Food safety education is a critical element of the risk analysis framework, which includes risk assessment, risk management, and risk communication. It is a risk management strategy because educating food preparers is an important way to reduce the risk of foodborne illness. Education is also a risk communication function because it serves to alert the public about a hazard that exists and can be addressed by safe food handling and food selection.

As we continue to examine emerging and existing food safety problems, it is important that we remember that reducing foodborne illness requires numerous interventions all along the farm-to-table chain. We must consider all the strategies available to us—and education is one of them—to make the food supply safer. That is why we continually look for the most cost-effective ways to get the food safety message out to all food handlers from coast to coast.

I have been busy travelling around the Nation conducting media interviews and delivering food safety education messages through an aggressive campaign. This is why we have pursued an even greater amount of coordination among government, industry, and consumer groups to deliver food safety messages to all food handlers and preparers.

One of FSIS' key public health missions is to educate the public about the hazards of foodborne illness, as well as to teach safe food handling techniques to ensure the safety of meat, poultry, and egg products. Since we are trying to share our food safety message with all segments of the population, such as consumers, food preparers, educators, children, physicians, public health officials, and industry, this is a formidable task.

Because we are tasked with spreading our food safety message to so many people with a limited amount of resources, FSIS is developing a comprehensive and sustainable mass media campaign that leverages traditional and non-traditional media outlets throughout the country to get this important message out. To carry out this function, FSIS has requested $1.5 million in the fiscal year 2004 budget for the development of this food safety education campaign. Some of the funds will be used to consult expert assistance on the design of a mass media food safety campaign. The agency intends to combine the expertise of the consultant with that of its traditional food safety education partners, as well as others with expertise in the delivery of public health and food safety messages.

The development of this food safety campaign is the next step in the agency's efforts to continuously enhance the delivery of important and life-saving food safety messages to the public. Currently, FSIS Food Safety Education staff is working with traditional media sources, food handlers and preparers, as well as other "food safety education audiences" to refine food safety messages and lay the groundwork for future development of a wider mass media education campaign.

To this end, the agency is sending the USDA Food Safety Mobile to strategic locations throughout the country to research and develop this important food safety education campaign. While delivering important food safety messages to the public, the Mobile is providing valuable first hand insight on how future mass media messages and education campaigns should be constructed and delivered. FSIS will combine this research with the expert consultation it will seek in fiscal year 2004 from food safety education professionals and develop a much broader and sustainable mass media campaign.

Also last year, FSIS partnered with the Food and Nutrition Service to provide new educational materials to schools and child care facilities. We are also actively engaged in the Partnership for Food Safety Education, which is a public-private coalition dedicated to educating the public about safe food handling preparation to help reduce foodborne illness.

We all have to realize as well that education is not just about the basics of food handling. There are many new effective products and technologies in the marketplace that can be used to reduce pathogens and food preparers need to be educated about them. Basic and thorough education is needed to inform and change possible misconceptions about their applications.

Irradiation is a good example of a technology that is misunderstood by the public. We were charged by Congress in the recent Farm Bill to conduct an education program on the availability and safety of new technologies, including irradiation, that eliminate or substantially reduce the levels of pathogens in meat and poultry products. Last year we convened a meeting with a group of the foremost experts on pasteurization/irradiation to start developing an education program. We expect much to come out of this group as we continue to develop and deliver an effective education program for pasteurization/irradiation.

Efforts to Improve International Safety

The U.S. food safety system is the gold standard for the world. Because we have the same safety requirements for the U.S. meat and poultry produced for export and for products entering the United States, our efforts to continually improve our food safety system have a global impact.

We are fully committed to working with our international partners in ensuring a safe global food supply. Under my direction, the Office of Food Safety leads the U.S. office of the Codex Alimentarius Commission, which is an international standard-setting body for food safety. Our active leadership in Codex contributes to decisions that have profound effects on national economies and the health and well being of citizens around the world. That is why FSIS strives to educate the public, our U.S. partners, and interested partners around the world about the important role Codex plays in developing science-based global food safety standards. It is in our national interest to maintain our leadership role in Codex in order to ensure food safety regulations around the world are reasonable, equitable, and achievable.

Another example of our commitment to international food safety is through education. Last year, we cosponsored with the U.S. Department of Health and Human Services the "Thinking Globally—Working Locally: A Conference on Food Safety Education." The conference included breakout sessions, workshops, and tours focusing on the food safety education implications of the global food supply. Over 600 participants from the United States and abroad attended.

We also reached out to rural women worldwide through participation in the Third International Congress on Women in Agriculture held in Spain last year. We delivered our food safety education message at this conference to help strengthen our message throughout the world.

Risk Assessment

While FSIS has been able to use risk assessments to better shape our policy, we also need to make sure that the risk assessments that we carry out address the agency's needs. Our talented and dedicated leadership team has made it clear to the FSIS workforce and to industry that science will dictate our food safety programs. At the moment, there is no formal infrastructure for science-based policy making. We are working hard to rectify this. You cannot craft a solution in this highly complex food production world if you have not specifically identified the problem.

We need a central, state-of-the-art source for the development of risk assessment models. We are working now on designing such a plan. It is getting increasingly difficult to manage a threat when we are unsure of its pervasiveness. Risk assessment provides this vital data. The benefits of using risk assessments can be seen in our recent initiatives on E. coli O157:H7 and Listeria monocytogenes that I discussed earlier. This process needs to be strengthened, formalized, and continually supported in order to be used to its full potential. By strengthening the agency's reliance on risk assessments to shape future policy, we will be better prepared to fight the war on pathogens.

To be effective, we need to both analyze current threats to the food supply and anticipate problems that may arise. There are times when we work in a completely reactive mode and I do not think this serves us well when we try to anticipate new challenges.

I am well aware that there are gaps in our current universe of food safety research and until we close the gaps we will not be able to fully understand, or control, the farm-to-table continuum. We need to bring the brightest food safety minds from throughout the country together in a way that will help the Federal government, industry, foodservice and the American people.

Validated Decontamination Methods

We need to focus on the application of validated decontamination methods in order to reduce pathogens. A conscious effort has been made when drafting FSIS' Notices and Directives to encourage industry to utilize new decontamination technologies. Scientific and technical innovation that keeps our food safer should be encouraged. Therefore, we intend to consider further ways to validate these technologies in order to ensure their ability to reduce foodborne pathogens.

We believe that new technology provides a great opportunity to enhance the safety of meat, poultry, and egg products. Thus, the agency continues steps to encourage and provide opportunities for technological advances and innovation under the PR/HACCP rules. We recently announced new procedures for new technology intended for use in establishments. These procedures were designed to encourage innovation by eliminating undue delays in the development, testing, and use of new technology. This will allow FSIS to respond efficiently and expeditiously when technological innovations become available and help, not hinder, in the implementation of these food safety tools.

Initiatives from the fiscal year 2004 Budget Request

At this time, I would like to focus on the initiatives of the fiscal year 2004 food safety budget request and indicate how this additional funding will help us reach our goals. I firmly believe these resources will help us make the necessary improvements aimed at protecting the health and safety of the public we serve.

The fiscal year 2004 budget request supports FSIS' basic mission of ensuring continuous inspection in each meat, poultry, and egg products establishment in our country and reinspection of imported product. It also reflects President Bush's deep concern about ensuring a strong food safety system. His record level budget request for food safety programs will allow FSIS to continue working to fully implement the goals we have laid out, but will also allow us to pursue new initiatives.

USDA's food safety budget requests a program level of $899 million, an increase of $42 million over the enacted level for fiscal year 2003. This funding represents a $148 million, or 23 percent, increase for USDA food safety activities since fiscal year 2000. The $42 million increase in the fiscal year 2004 budget to strengthen FSIS' food safety program encompasses $23.6 million in increases to cover raises in employees' salaries and benefits, the costs of inflation, and FSIS' support of State-inspection programs.

The other part of the budget increase covers $19.3 million in initiatives to fund the hiring of more food safety inspectors, provide specialized scientific and technical training for the inspection workforce, increase microbiological testing and sampling, strengthen foreign surveillance programs, and increase our public education efforts.

As I mentioned, it is absolutely necessary that we use science to improve food safety. One of the ways the President's budget helps us do that is through the $1.7 million to do baseline studies on a variety of pathogens, including E. coli O157:H7. This funding will strengthen the backbone of effective policy making by allowing us to collect data on the presence of microbial hazards, which is a crucial component used in developing risk assessment models.

Another means of employing science is the strategy of equipping our frontline workforce with scientific and technical expertise. The $5.7 million requested in the President's budget will help us expand our in-depth HACCP and Sanitation Standard Operating Procedure (SSOP) training to all of our veterinarians and inspectors. With these resources, we will be able to increase consistency, effectiveness and accuracy of food inspection, thus making our food safer.

Along with this notion of a well-trained inspection workforce, is the fact that FSIS needs to have a full complement of inspectors. For this purpose, the President's budget requested $4.3 million in funding to increase our workforce to 7,680 in-plant staff by adding 80 new positions. These 80 positions are necessary to ensure continuous inspection of all meat, poultry, and egg products plants.

When a foodborne outbreak occurs, it is essential to identify the source of the outbreak so that the agency can take swift action to prevent further illnesses and warn the public of the adulterated product. Therefore, the fiscal year 2004 budget request includes $4.5 million to provide additional microbiologists, chemists, laboratory technicians, and other personnel to increase the agency's ability to identify adulterants in meat, poultry, and egg products. This funding will help the agency develop analytical methods to test food products for chemical, biological, and radiological contamination. This initiative will also increase sampling of ready-to-eat products for the presence of bacteria such as Listeria monocytogenes and Salmonella. With this funding, FSIS will increase sampling of these products from 10,000 to 15,000 annually and will add the capability to conduct 5,000 Listeria monocytogenes environmental samples annually. The agency also plans to increase sampling of raw ground

beef and raw ground beef ingredients for E. coli O157:H7 from 7,000 to 15,000 samples annually.

Additionally, the President's budget includes $1.8 million to increase the number of foreign program auditors, thereby strengthening our oversight at the location where the food is actually produced or manufactured for export to the United States. This augments our existing strong system of ensuring that imported food is safe.

Our public education effort, which I discussed earlier in our five goals, is one avenue we are aggressively taking to make sure that all food handlers and preparers follow safe food handling practices to reduce foodborne illness. The President's budget request for an additional $1.5 million for food safety education will allow the agency to continue to research and develop a sustainable and comprehensive mass media campaign across the country.

Finally, the fiscal year 2004 budget request includes a proposal to recover the costs of providing inspection services beyond an approved eight-hour primary shift. FSIS already collects $102 million in reimbursable fees to recover the costs associated with overtime, holiday, and voluntary inspection services. FSIS has submitted legislation to Congress to allow the agency to collect user fees for inspection services beyond one approved eight-hour shift per day. If approved by Congress, it will enable the agency to collect approximately $122 million in user fees and reduce our appropriated request from $797 million to $675 million. This will result in a savings for the American taxpayer.

Closing

In closing, I want to emphasize that we already have a strong food safety infrastructure in place. We have made great progress in achieving the goals we have set for ourselves. We have a strong leadership team to direct us toward improving our ultimate goal of protecting public health.

The President's budget for fiscal year 2004 provides us with a historic opportunity to—not only do what is right—but to do what is needed, which is to employ science to its fullest potential to make food in the United States as safe as possible. With the support and assistance of this Administration and Congress, I am confident we can do just that.

This concludes my written statement. I want to thank the Chairman and Members of the Subcommittee for the opportunity to testify on behalf of USDA's Office of Food Safety. I welcome your questions.

Prepared Statement of Garry L. McKee, Administrator, Food Safety and Inspection Service

Mr. Chairman and Members of the Subcommittee, I am pleased to have the opportunity to provide a statement on the current status of Food Safety and Inspection Service (FSIS) programs and on the fiscal year 2004 budget request for food safety within the U.S. Department of Agriculture (USDA).

Before I move into the details of my statement, I'd like to take this opportunity to introduce myself, since this is my first time before the Subcommittee. I've been with FSIS for a short period of time. Although I came to FSIS from the Wyoming Department of Health, I am a proud Oklahoman at heart. I graduated from Southwestern Oklahoma State University and the University of Oklahoma, concentrating on microbiology and public health. Having been in the public health field for more than 30 years, I am very comfortable with the public health mission of FSIS.

Today I would like share with you the steps FSIS is taking to become a world-class public health agency. These will include:

—FSIS' Year in Review;
—Three Functions of a Successful Public Health Model;
—FSIS Accomplishments Towards Becoming a World-Class Public Health Agency;
—FSIS Partnerships; and
—The proposed fiscal year 2004 FSIS Budget.

FSIS' YEAR IN REVIEW

If you would allow me a moment, I would like to share some of FSIS' accomplishments over the past year so you can gain a better understanding of the way our budget is structured. As you know, under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS inspects meat, poultry, and egg products sold in interstate commerce and reinspects imported products, to ensure that they meet U.S. food safety standards.

It is FSIS' mission to ensure that all meat, poultry, and egg products for use as human food are safe, secure, wholesome, and accurately labeled. More than 7,600

inspection personnel verify that regulations regarding food safety, and other consumer protection concerns, such as labeling, are met in over 6,300 Federal meat, poultry, and egg processing plants, each and every day they are in operation. FSIS has jurisdiction over products that generate more than $120 billion in sales, which represents one-third of all consumer spending on food. In addition, since September 11th, our workforce has been on heightened alert and is diligently monitoring all of these plants to ensure that there is no intentional biosecurity breach that could harm our Nation's food supply.

Throughout 2002, FSIS was hard at work, protecting the safety of meat, poultry, and egg products. In fiscal year 2002, FSIS inspectors monitored the processing of 92.6 billion pounds of meat and poultry and inspected 3.7 billion pounds of liquid egg products. Inspectors at our 110 import inspection stations monitored the importation of 3.9 billion pounds of meat and poultry products from 27 of 33 foreign countries meeting U.S. equivalency requirements and choosing to import to the United States last year. FSIS also facilitated the exportation of over 11 billion pounds of meat and poultry products worth $7.5 billion to over 100 countries. In addition, FSIS spread the food safety message to approximately 90 million people through the media, the FSIS web site, and the USDA Meat and Poultry Hotline. FSIS also diligently continued its duty of protecting the public health, by overseeing the voluntary recall of any meat, poultry, and egg products that may have been potentially contaminated. As you can see, we have had quite a busy year.

IMPROVING PUBLIC HEALTH

I have spent my entire career in this field and am devoted to administering under its protocols and scientific foundations. Public health is my number one priority. Thus, we are building FSIS into a recognized, credible, world-class public health agency that is a model for all other public health institutions.

What does a "world-class" public health agency mean? Frankly, it means that we need to be the experts in improving the safety of meat, poultry, and egg products for the American people. We must also ensure that our food supply is safe and secure from bioterrorist attacks, intentional tampering, or other forms of adulteration. While I believe that FSIS has made considerable progress towards these goals, more can be done to make this agency the top-notch public health regulatory agency we envision it can be. All of the nearly 10,000 employees at FSIS are committed to achieving this vision.

Three Functions of a Successful Public Health Model

In order to make FSIS a world-class public health agency, there are three parts of a successful public health model that FSIS must implement. First, FSIS must assess public health problems using science, such as surveillance, data collection, monitoring, risk assessment, and forecasting trends. Dr. Murano and I believe that science is the absolute best and most reliable tool we have to address the public health issue of food safety. In order to accomplish our goals, we must continue to make significant, science-based policy improvements that can measurably improve public health. By relying on science in our decision-making, we take the guesswork out of our policy-making process. Science is the weapon that will lead our workforce to victory in our declared war on pathogens.

Our assessment activities will help FSIS carry out the second part of a successful public health model, which is policy development. FSIS must continue to develop and implement policies to reduce the risk of foodborne illnesses using science-based knowledge. Once we identify a problem or hazard, we need to craft an effective solution. As a public health agency, we are equipped for this problem-solving role with our technical knowledge and expertise. Policy development activities include planning and priority-setting, the development of regulations, directives, and other policy vehicles, mobilizing resources, training, constituency building, distribution of public information, and encouragement of public and private sector cooperation.

Finally, FSIS must assure the American public that we are carrying out our jobs effectively through enforcement of established statutory and regulatory responsibilities. We will hold industry, as well as ourselves, responsible for ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled. By successfully carrying out our food safety mission, we are assuring the public that the USDA mark of inspection found on meat, poultry, and egg products means what it says.

By carrying out these functions, FSIS is protecting the public from foodborne illnesses. But, protecting public health also means ensuring the security of our food, which is a vital component of Homeland Security—a growing source of concern. The tragic events of September 11th, as well as current threat assessments, have made Americans more aware that the unthinkable could become a reality. Biological, chemical, and radiological threats to our Nation's food supply are plausible from

those intent on harming our Nation through any possible means. Since the terrorist attacks on America, food security has been the highest priority at FSIS and we continue to take steps to ensure that we are prepared to prevent and respond to any potential or actual threats to our Nation.

Now I'd like to share with you some specific examples of how FSIS is ensuring the safety of our meat, poultry, and egg products.

BETTER ADDRESSING PATHOGENS

E. coli O157:H7

The issue of E. coli O157:H7 in ground beef emerged in the 1990s and FSIS' microbiological testing program to detect E. coli O157:H7 in raw ground beef began in October 1994. Since then, over 57,000 raw ground beef samples have been analyzed. Each month, a random sample from the approximately 1,700 establishments that produce ground beef under FSIS inspection and the 100,000 retail stores that grind beef on a regular basis, are selected for sample collection. In 2002, over 7,000 samples were analyzed for E. coli O157:H7. Since FSIS' E. coli O157:H7 testing program began, it has been continuously amended to incorporate the most up-to-date data and technologies.

Data from the Agricultural Research Service (ARS) and the Centers for Disease Control and Prevention (CDC), as well as FSIS' draft risk assessment of E. coli O157:H7, indicated that E. coli O157:H7 was more prevalent than previously believed. The data led FSIS to further strengthen its E. coli O157:H7 policies and implement additional safeguards to increase food safety. In an October 2002 Federal Register Notice, FSIS published a series of new measures designed to reduce the incidence of E. coli O157:H7 contamination in raw ground beef. For instance, all facilities handling raw ground beef must reassess their Hazard Analysis and Critical Control Point (HACCP) plans and decide whether E. coli O157:H7 is a pathogen reasonably likely to occur in their products. In addition, establishments that receive product for grinding may determine that no additional steps are necessary at grinding facilities to address E. coli O157:H7, but only if appropriate purchase specifications are built into their food safety system. However, these specifications require that all suppliers must have one or more validated critical control points to eliminate or reduce E. coli O157:H7 below detectable levels and some means to ensure that these specifications are met.

FSIS has set deadlines for completion of the reassessments, in order to ensure that all plants have reassessed their HACCP plans to account for E. coli O157:H7. Large plants, those with 500 or more employees, were required to comply by December 6, 2002; small plants, or those with less than 500, by February 4, 2003; and very small plants, those having fewer than 10 employees or annual sales of less than $2.5 million, were required to comply by April 7, 2003. FSIS Consumer Safety Officers (CSO) are completing extensive scientific reviews of plant HACCP plans and Sanitation Standard Operating Procedures (SSOPs) to ensure the reassessments are successfully addressing E. coli O157:H7 concerns, as well as all other aspects of HACCP regulations.

FSIS is also modifying its current E. coli O157:H7 sampling and testing program to include all plants. In the past, FSIS did not typically collect raw ground beef samples at establishments that conducted their own E. coli O157:H7 testing. However, FSIS has found that, in spite of this private-sector testing, some of these establishments have had problems with E. coli O157:H7 contamination. In response, FSIS issued a notice on April 18, 2003, to revise its current directive to discontinue all exemptions from FSIS sampling and testing for E. coli O157:H7.

FSIS is also developing a risk-based verification program that takes into account factors such as volume of production and effectiveness of interventions in determining testing frequencies. In addition to continuing to test for E. coli O157:H7 in ground beef, FSIS is considering testing for E. coli O157:H7 in trimmings and other intact materials used in non-intact product and beef carcasses and parts that will be processed into non-intact product. We believe that controls to reduce the risk of E. coli O157:H7 on intact product may be among the most effective ways to control the hazard overall and that these changes are critical to protecting public health.

Listeria Monocytogenes

Following a recent voluntary recall of ready-to-eat poultry products due to potential contamination with Listeria monocytogenes, FSIS implemented a new policy to improve testing programs for Listeria monocytogenes in the environment of plants producing ready-to-eat products, such as deli meats and hot dogs. In November 2002, the agency released a directive announcing that plants producing high- and medium-risk, ready-to-eat products that do not have a scientifically-based, validated

program in place for the control of Listeria monocytogenes, will be subject to an intensified FSIS testing program. In December 2002, the agency completed a survey to identify plants that will be considered for intensified testing. This new risk-based policy will allow FSIS to confirm an establishment's commitment to zero tolerance for Listeria monocytogenes on product and product contact surfaces.

On February 14, 2003, FSIS released its draft risk assessment that provides a vital tool to estimate the public health impacts of various control measures for reducing the risk of Listeria monocytogenes. This draft risk assessment suggests that a combination of testing, sanitation, and other interventions exhibited greater benefits than when each step was used alone. It also suggests that product contact testing, used in conjunction with enhanced sanitation procedures, can lead to a reduction in Listeria-related illness. In addition, the risk assessment demonstrated that the use of intervention steps, such as post-packaging pasteurization or the introduction of growth inhibitors, showed dramatic public health benefits.

FSIS utilized information gained from the risk assessment to proceed on an effective regulatory approach to reduce Listeria monocytogenes in processing plants producing ready-to-eat meat and poultry products. FSIS is working to publish a final rule for Listeria monocytogenes in ready-to-eat products and hopes to have it ready as quickly as possible.

Scientific Symposia

We have also greatly increased our efforts to incorporate a broad range of scientific thinking on food safety issues in order to effectively combat harmful pathogens. In 2002, FSIS initiated a series of nine scientific symposia aimed at generating dialogue on important issues among public health experts, industry, advocacy groups, consumers, academia, and the public. These meetings allowed the agency to gather input on what scientific solutions would best address public health concerns. For example, FSIS held a scientific symposium on pathogen reduction in May 2002, to discuss the appropriate role of microbial testing in food safety and other food safety concerns. In November 2002, the agency held a Listeria summit to discuss the public health impact of Listeria monocytogenes. In February, the agency held a meeting to discuss the results of the draft risk assessment on Listeria monocytogenes. And just last month, we held a public meeting to discuss the agency's use of epidemiology as a basis for regulatory decision making. We believe the symposia allowed us to be as inclusive as possible, as well as gain valuable information and insight. Therefore, the agency has planned additional symposia in fiscal year 2003 on such topics as risk analysis, and HACCP and poultry processing.

PUBLIC HEALTH MANAGEMENT

A world-class public health agency must run like clockwork in order to quickly and successfully prevent or respond to food safety emergencies. This requires a common dedication and focus at all levels, from headquarters management to the frontline employees in plants in the most rural parts of America. Therefore, FSIS has implemented an array of measures over the past year to enhance accountability, build professionalism, and ensure a coordinated public health approach to food safety.

FSIS Reorganization

On our way to becoming a world-class public health agency, it became apparent that the structure of FSIS needed to be reorganized to efficiently and effectively meet our goals, carry out our critical functions, and protect public health. I have made it a top priority to restructure the agency in a way that prepares FSIS to meet its public health and food safety goals in a logical and streamlined fashion. This reorganization will increase accountability for all FSIS employees and refocus the duties of many employees.

The reorganization will ensure that the principles of public health and food safety cut across the entire spectrum of FSIS' critical public health mission. We have added four assistant administrators in key areas—for Food Security; Program Evaluation, Enforcement, and Review; Communication, Outreach, and External Affairs; and International Coordination. These additions will strengthen the bonds between our various offices and make our operational models more coherent and responsive. For example, the assistant administrator of Food Security will tie together all Homeland Security activities within the agency, so that our policy makers, our scientists, our field staff, and our management are all working together to ensure that we are prepared to prevent and respond to any bioterrorist attack.

Program Evaluation, Enforcement and Review

In fiscal year 2002, FSIS created the Program Evaluation, Enforcement and Review (PEER) office to serve as the agency's quality control team. This office's mission is to ensure that effectiveness, efficiency, consistency, and accountability become the rule at FSIS. This new office will ensure that FSIS functions such as reviews of plants for compliance and food safety investigations are carried out in a way most conducive to protecting the public health. This office also conducts program audits, reviews, assessments, and evaluations in an effort to ensure that they are performing as needed or uncover difficulties early on, before they reach the problem stage. Lastly, this office also helps ensure that the agency has an effective, efficient, timely, and aggressive program for dealing with those who violate the meat and poultry laws.

Improved Communications

Our food safety message is most effective when every person along the farm-to-table continuum is aware of its importance and, just as importantly, understands it. As part of the FSIS reorganization, we created the Office of Communication, Outreach, and External Affairs. This office is tasked with spreading the food safety message to our many constituents whether in Congress, industry, advocacy groups, the public, or the media. We devote a great deal of energy and resources into translating highly technical food safety information and making it accessible and understandable at many different levels. But communication is a two-way street and we make every effort to receive and process input from our constituents so that we are aware of, and sensitive to, their range of viewpoints. We are always looking to improve our public health mission and communication is one of our most critical tools.

Automated Import Inspection System

FSIS is also improving its management effectiveness on the international level. All imported meat and poultry is inspected in its country of origin, as well as visually reinspected by FSIS before being released in the United States. Additionally, FSIS tests imported products for residues, microbiology, and food chemistry. In fiscal year 2002, FSIS introduced the new Automated Import Information System (AIIS). This system focuses on a foreign country's inspection system as a whole, rather than on individual plants, to statistically choose imports for reinspection based on the annual volume of shipments from the exporting country. Previously, for all countries except Canada, reinspection was randomly assigned based on an establishment's compliance history. The new system is user-friendly and allows inspectors at all ports-of-entry to share data. It also allows managers to have instant access to inspection reports. The new AIIS system also provides better tracking of shipments once they enter the United States. The next step is for FSIS to integrate our system with USDA's Animal and Plant Health Inspection Service (APHIS) and the U.S. Customs systems to further strengthen the food safety system against intentional attacks.

WORKFORCE AND TRAINING INITIATIVES

Our workforce is the backbone of FSIS. We rely on our field employees to be in every meat, poultry, and egg products plant, ensuring that the plants are producing products that are safe, wholesome, and accurately labeled. Our frontline employees are the ones we rely on to make the critical determination that products are not adulterated and are safe to eat. They are also responsible for identifying and preventing intentional threats to the food supply. For this reason, I have made training my top priority as FSIS Administrator. I am personally overseeing the changes the agency is implementing in our training programs and believe it is absolutely critical that we have a scientifically- and technically-trained workforce that is dedicated to ensuring a safe supply of meat, poultry, and egg products. A well-trained and competent workforce is a key element to making any institution successful. I am committed to achieving the aggressive public health goals we have set at FSIS through improving our employees' skill level, which will in turn, make us better guardians of the public health and safety.

Consumer Safety Officers

Let me give you an example. To achieve our public health goals, FSIS recognized the need for frontline employees to have a scientific and technical background. Therefore, the agency created the Consumer Safety Officer (CSO) series to reflect our increasing reliance on science and technology. CSOs have a scientific and technical background and receive additional agency training that enables them to assess and verify the design of food safety systems. FSIS trained 104 employees as CSOs in fiscal year 2002, and plans to train an additional 105 in fiscal year 2003. The

agency is extending CSO training to its Veterinary Medical Officers (VMOs) to raise scientific and technical knowledge within the agency.

Humane Handling and Slaughter Initiatives

We have also strengthened our workforce's ability to enforce the HMSA. All of the over 7,600 FSIS inspection personnel are expected to enforce the Humane Methods of Slaughter Act (HMSA) and take enforcement action for humane handling and slaughter violations. FSIS has inspection personnel trained in humane methods of handling and slaughter in all of the nearly 900 federally inspected U.S. livestock slaughter establishments. In addition to their food safety-related inspection responsibilities, these veterinarians and inspectors are charged with observing the methods by which livestock are slaughtered. FSIS inspectors and veterinarians, who provide continuous inspection in every slaughter facility, are required to take immediate enforcement action when a violation is observed. FSIS personnel who fail to enforce the HMSA are considered negligent in their duties and are subject to disciplinary action. FSIS has taken, and will continue to take, enforcement actions against plants that do not follow humane handling requirements.

In addition, FSIS used funding allocated in the fiscal year 2001 Supplemental bill to hire 17 veterinarians to serve as District Veterinary Medical Specialists (DVMS) in each of the agency's districts. The DVMS reported for duty on December 30, 2001. The DVMS have been trained in all aspects related to humane handling and slaughter, including antemortem inspection, humane handling regulations, the HMSA, stunning methodologies, assessing consciousness, enforcement procedures related to humane handling, and workplace violence. They also serve as the program coordinators for all humane handling issues within their districts and are providing training to newly hired in-plant VMOs on the agency's humane handling and slaughter responsibilities.

Chief Veterinarian

In fiscal year 2002, FSIS established a Chief Veterinary Medical Officer position to promote the education, training, and professional development of the agency's approximately 1,100 veterinarians. In addition, FSIS veterinarians have completed a survey to determine what skills they possess and to help the agency assess how it can harness their skills to help meet its ever-evolving goals.

Inspection Coordinator Training

Becoming a world-class public health agency requires that FSIS increase technical training and the scientific expertise of our workforce. Inspection Coordinators (ICs) in each District were trained to increase their HACCP expertise, particularly with respect to HACCP plan design and scientific support for HACCP plans. The ICs often participate in, or lead, in-depth verification reviews (IDVs) to assess whether an establishment is carrying out activities that meet requirements of the FSIS Pathogen Reduction (PR)/HACCP rule. This training will enhance their ability to do a more effective job and will also provide Districts with an additional resource capable of conducting comprehensive food safety assessments. In response to a Government Accounting Office recommendation that FSIS strengthen basic training for its inspectors, the agency has begun to reinforce HACCP, SSOPs, and Sanitation Performance Standards knowledge, through training of its entire in-plant workforce. In April 2003, the agency's Consumer Safety Inspectors began this food safety regulatory essentials training. I will discuss in greater detail this key aspect of our fiscal year 2004 budget request in a moment.

Compliance Officer Training

In fiscal year 2002, FSIS conducted a Compliance Officers (COs) training program at the Federal Law Enforcement Training Center in New Mexico. Nineteen Federal and three State COs completed the three-week course on basic safety training. In addition, sixty-one COs and three CSOs completed three specialized one-week safety courses, especially designed for FSIS. Also, twelve COs completed a one-week Instructor Verbal Judo Course designed to instruct them how to teach other employees how to better handle stressful situations they may encounter as part of their jobs. All of these training programs are the building blocks to the model public health agency I envision for FSIS.

In-Plant Performance System In October 2002, FSIS implemented the In-Plant Performance System (IPPS), which puts in place a formal process so frontline supervisors can be sure that inspection personnel carry out their assigned job responsibilities. All field supervisors have been trained to use this system. Performance reviews have resulted in several letters of caution and instruction to employees who were not performing at the expected level. More importantly, the reviews have high-

lighted what we are doing right, as well as steps we can take to make even more improvements.

HIMP

As you know, in 1997, FSIS initiated the HACCP-based Inspection Models Project (HIMP) pilot program. The goal of HIMP is to improve public health by enabling FSIS to maintain the same level of consumer protection with fewer inspectors tied to the slaughter line, thus resulting in more intense and effective inspection and verification activities. In June 2002, FSIS made data from the National Alliance for Food Safety (NAFS) available comparing HIMP and traditional inspection, which indicate that HIMP is at least equal to the traditional inspection system. In September 2002, an independent review of the HIMP data concluded that "the HIMP system compared favorably to the traditional system of inspection." FSIS is encouraged by this data and we intend to use these results to further modernize our inspection system to most effectively prevent and control food safety hazards. Homeland Security Training FSIS has also initiated a comprehensive 2-year training and education effort designed to ensure that every FSIS employee fully understands his or her role and responsibility in preventing or responding to an attack on the food supply. In addition, FSIS has developed multimedia tools covering food security initiatives, emergency response procedures, and guidelines for food processors for use in training all frontline supervisors. These have been shared with our State and local partners, as well as industry, to address their biosecurity awareness and training needs.

In addition, FSIS personnel have been trained in the application of the agency's voluntary food security guidelines. This guidance promotes an exchange of information between FSIS, industry, and other agencies such as the Food and Drug Administration (FDA), on the subject of food security, as well as heightens industry's awareness of food security practices. FSIS is also working in cooperation with other Federal and State agencies such as APHIS, CDC, the Environmental Protection Agency, and the Department of Defense to develop biosecurity plans and training programs to identify and minimize food security risks.

HOMELAND SECURITY EFFORTS

The events of September 11th and subsequent vulnerability assessments revealed the need for a more integrated and coordinated plan to protect meat, poultry, and egg products. Immediately following September 11th, FSIS established the Food Biosecurity Action Team (F–BAT), charged with coordinating all activities pertaining to biosecurity, countering terrorism, and emergency preparedness within the agency. These activities are coordinated with USDA's Homeland Security Council, other government agencies and industry.

Office of Food Security and Emergency Preparedness

The creation of the Office of Food Security and Emergency Preparedness took over F–BAT's role as the centralized office within the agency that serves as an interface with USDA's Homeland Security Council and represents the agency on all food security matters throughout the Federal government as well as State and local activities. The Office's mission is to prepare for, prevent, and coordinate a response to intentional acts and other major events threatening the U.S. food supply. It is comprised of two staffs, an External Relations and Emergency Preparedness Staff, in addition to a Scientific and Technical Support Staff. The External Relations staff's primary responsibility is to develop and maintain the extensive network of Federal and State relationships necessary to mobilize for a food-related emergency. The Scientific staff provides science-based support for emergency response and prepares contingency plans for minimizing risk to the safety and security of the food supply, as well as to first responders.

Tabletop Exercises

FSIS has conducted a number of simulation exercises at the Federal, State, and local levels to test its preparedness and response to an attack on the food supply. These exercises give agency employees the opportunity to simulate their actions in response to a threat on the food supply. One exercise earlier this year, "Crimson Winter," proved very successful because it allowed the agency to recognize and correct vulnerabilities in its Homeland Security response plans.

Bioterrorism Vulnerability Assessment for Domestic and Imported Products

FSIS has conducted a food security vulnerability assessment to be used for determining the most vulnerable products, likely agents, and potential sites for deliberate adulteration of domestically produced meat, poultry, and egg products. The assess-

ment was conducted using a farm-to-table approach based on current knowledge of the industrial processes used in the production of these products and the potential biological and chemical agents that could be introduced. The assessment was concluded in June 2002, and the information obtained is being used to develop risk management strategies, including ensuring that our laboratories are equipped with methods and personnel for detecting agents of concern.

A vulnerability assessment of the import system is also being developed to identify points in the production of imported products where biological, chemical, and radiological contaminants could be intentionally added to foods being brought into the United States. FSIS used the risk analysis framework to conduct a relative risk ranking to be used to allocate resources to monitor U.S. ports of entry for those food commodities that pose the greatest risk, examine different intervention strategies for preventing or reducing risks, develop biohazard identification protocols, and target training of personnel and develop educational campaigns to increase awareness. This assessment is expected to be completed in September 2003.

Import Surveillance Liaison Inspector

Soon after the terrorist attacks on the United States, FSIS inspectors nationwide were placed on heightened alert, a condition that remains in effect today. Using funds provided by the fiscal year 2001 Homeland Security Supplemental Appropriations bill, FSIS created a new position, that of the import surveillance liaison inspector. As of March 1, 20 new import inspectors are on duty at ports of entry to augment the efforts of traditional FSIS import inspectors assigned to the 146 import establishments in the country. Where traditional USDA import inspectors examine each shipment and conduct reinspection activities, these new import surveillance liaison inspectors conduct a broader range of surveillance activities at each import facility, as well as extensive records review. These inspectors not only improve the agency's ability to ensure the safety of imported meat, poultry, and egg products, but as liaisons, they also improve our coordination with other agencies (e.g., U.S. Customs, APHIS) concerned with the safety of imported food products. We are looking at ways, in the future, to both increase the number of liaison officers and to expand and enhance their roles.

FSIS Food Security Initiatives

In early February 2003, FSIS released a report titled, Protecting America's Meat, Poultry and Egg Products. The report, prepared by the Office of Food Security and Emergency Preparedness, outlines FSIS' food security initiatives. Some of the initiatives included in the report are assessing potential vulnerabilities along the farm-to-table continuum, enhancing security features at all FSIS laboratories, and strengthening FSIS coordination and cooperation with law enforcement agencies.

FSIS PARTNERSHIPS

FSIS plays an essential role in ensuring that the meat, poultry, and egg products that we eat are safe. While we mainly focus on the processing of these products, we have a responsibility to the American people to make sure that the entire food chain is strong. Food safety is a team effort and we are always working to strengthen all the links in this food chain. However, it requires that everyone involved in the process, from the farmer to the consumer, carries out his or her responsibility in ensuring that the food we eat is safe and safely prepared. FSIS works with industry, consumers, and our sister agencies on a daily basis in this effort to reduce to the greatest extent possible foodborne contamination.

Industry Outreach

FSIS strives to maintain a healthy and direct relationship with the meat, poultry, and egg products industries. We work with industry to prevent harmful pathogens from entering the food supply. FSIS was there to provide guidance when the HACCP program was first implemented, and we continue to provide guidance to help plants correctly implement the program through our veterinarians, on-line inspectors, and consumer safety officers. But now that HACCP has been introduced and implemented, we are in the next phase, which is enforcement. We will hold industry, and ourselves, responsible for successfully operating under the PR/HACCP model.

In fiscal year 2002, FSIS made significant achievements in its Small and Very Small Plant Outreach Program. This program, introduced in 1998, was designed to develop and provide technical guidance and assistance to meet the specific needs of small plants, with ten or more employees, but fewer than 500, and very small plants with fewer than 10 employees, or annual sales of less than $2.5 million. FSIS held more than 30 courses targeting these segments of the industry across the country.

The courses focused on HACCP food safety systems and were provided through cooperative agreements with nine universities.

Part of the agency's outreach effort also includes keeping the meat, poultry, and egg products industry informed of changes and innovations in food safety, as well as the standards and requirements they must meet to operate a safe food production facility. In fiscal year 2002, FSIS made improvements to the agency's labeling and standards policy web site, which was introduced in 2002 as a new, business-friendly web site providing essential information to small and very small plants. The site is geared towards helping small businesses understand the fundamentals of labeling and standards and to provide a key contact on our staff to answer related questions. FSIS also provides a staff liaison charged with facilitating resolution of small business issues on a one-on-one basis. The Labeling Policy Staff receive over 400 inquiries a month for labeling guidance.

In May 2002, FSIS published voluntary security guidelines to assist Federal- and State-inspected meat, poultry, and egg products plants in identifying ways to strengthen their security plans to protect against acts of bioterrorism. FSIS provided these guidelines to field employees who will assist plants that seek further clarification or advice. They were designed for plants that may not have access to specialized security planning advice. These voluntary guidelines are available in English, Spanish, Vietnamese, Korean, and Mandarin Chinese, both in print and on the FSIS web site.

Food Safety Education

While a meat processing plant might produce a perfectly safe hamburger, innocent mistakes made by a food preparer could taint a product with harmful bacteria and create a potentially unsafe meal. Food can become contaminated at any step in the food chain. Thus, FSIS is committed to spreading the food safety message in order to further reduce the incidence of foodborne illness. Food safety education is certainly not a substitute for, but rather a complement to, science-based food safety policies. I would like nothing better than to tell people that they do not need to worry about how they handle and prepare their food because the government has taken care of the problem. But, as I said before, food safety is a team effort and must be carried out at all stages of the food production and preparation chain.

We will continue to strive for greater reductions in harmful pathogens in meat, poultry, and egg products production facilities. But regardless of what we can accomplish, food preparers always will have an important role in keeping food safe. Because of this, we have designed our FSIS food safety education programs to increase consumer knowledge and change behaviors in order to prevent foodborne illness. The agency develops educational materials based on up-to-date scientific and consumer research. Our programs target the general public, as well as those groups who face increased risks from foodborne illness—the very young, the elderly, pregnant women, people with chronic diseases, and people with compromised immune systems.

One of FSIS' key public health missions is to educate the public about the hazards of foodborne illness, as well as to teach safe food handling techniques to ensure the safety of meat, poultry, and egg products. Since we are trying to share our food safety message with all consumers, food preparers, educators, children, physicians, public health officials, and industry, this is a formidable task.

Because we are tasked with spreading our food safety message to so many with only a limited amount of resources, FSIS is developing a comprehensive and sustainable mass media campaign to most effectively utilize the agency's scarce resources. FSIS has requested $1.5 million in its fiscal year 2004 budget to seek expert assistance from an outside professional public relations firm to further develop and carry out this campaign.

FSIS has already started to develop this campaign with the new USDA Food Safety Mobile. The Food Safety Mobile is traveling the country to educate the public about the importance of food safety, but at the same time, we are learning important lessons about the best way to get our message across in order to reach the most people through events and the media. We will use the information that we learn from this new campaign to determine how to best utilize our resources and best meet our food safety education goals in the future.

FSIS also carried out a number of other food safety education campaigns in fiscal year 2002. In September, the agency held the "Thinking Globally—Working Locally: A Conference on Food Safety Education." The conference included breakout sessions, workshops, and tours focusing on the food safety education implications of the global food supply. Over 600 participants from the United States and abroad attended.

During its 18th year in existence, the USDA Meat and Poultry Hotline handled nearly 86,000 calls concerning safe food handling practices in the home. Last year,

the Hotline expanded its service to include recorded messages and live assistance in Spanish. In addition, the agency's two main e-mail addresses received over 5,200 inquiries and comments about food safety.

Coordination on International Activities

As one of several key U.S. agencies responsible for food safety, FSIS actively participates in developing international food safety standards through the Codex Alimentarius Commission. The U.S. Codex Office, under the leadership of the Office of Food Safety, is located within FSIS. The agency served as the head of U.S. Delegations to the Executive Committee of the Codex Alimentarius Commission meeting and to the Codex Committee on General Principles. In 2002, FSIS announced 17 public meetings on Codex standard setting activities and hosted foreign government officials at various workshops about important Codex issues.

Our leadership at Codex is instrumental in realizing global food safety standards are reasonable, equitable, and achievable. America is the gold standard for food safety programs. Successful participation in the Codex leadership is a vital national interest and will raise food safety standards around the world. FSIS remains committed to working through Codex to continue to stress the role of science in international standard setting.

Other Public Health Agencies

Because food safety is important at each stage in the entire farm-to-table continuum, FSIS works with other government agencies to make sure the U.S. produces safe meat, poultry, and egg products. We have partnerships with other Federal public health agencies, regulatory agencies, State governments, and research institutions, in order to share ideas and concerns, and maintain an open dialogue concerning food safety. By doing so, we are helping each agency achieve its respective vision, which ultimately helps us paint the big picture—improving public health.

Ensuring public health depends on scientific research. Food safety research carried out by ARS plays a critical role in assisting FSIS to evolve into a model public health agency. This is especially true because our environment is certainly not static. We constantly need to study the factors that change the prevalence rate of pathogens. These factors could be on the farm, around the farm, in transportation, at the plant, or en route to the consumer. ARS and FSIS work cooperatively to ensure that food safety research is appropriately addressed in USDA's research agenda.

An integral part of the fight against foodborne illness is early detection. In fiscal year 2002, FSIS completed its seventh full year of a partnership with the Department of Health and Human Service's CDC and FDA to track and respond to foodborne diseases in five States and parts of four more. This effort, called FoodNet, serves as an early warning system for foodborne illnesses. FoodNet, for the first time, identified a downward trend in the incidence of foodborne disease from 1996–2001. We look forward to continuing this partnership and learning more about foodborne illnesses in order to strengthen our efforts against them.

On April 17, 2003, FSIS signed a Memorandum of Agreement (MOA) with the U.S. Department of Health and Human Services' Public Health Service (PHS) Commissioned Corps, to expand the role and number of PHS Officers detailed to FSIS. PHS Officers are highly-trained health experts who bring diverse backgrounds and experience in support of the FSIS public health mission. Flexible deployment rules allow the PHS Officers to instantly respond to emergencies, such as a foodborne illness outbreak, and shifting priorities within the agency. This enhances FSIS capabilities for rapid response during heightened security alerts or an actual threat to food security. The new agreement will incorporate approximately 30 additional PHS Officers nationwide across all program areas in the agency where there is a greater demand for scientific knowledge and judgment. The PHS Officers will work as permanent staff members alongside their agency counterparts as veterinarians, scientists, dietitians, environmental health officers, physicians and nurses.

In fiscal year 2002, FSIS initiated eight cooperative agreements with States to raise awareness and understanding of the risks of handling meat, poultry, and egg products by retail stores and food service establishments. These agreements benefit those State and local agencies responsible for inspecting these establishments, as well as managers and owners. Additionally, FSIS field epidemiologists assisted local and State health departments with over 30 outbreak or emergency-related investigations due to such causes as E. coli O157:H7, Listeria, and Salmonella. Many of these investigations involved multiple States and localities.

In addition, as of July 31, 2002, FSIS can now share product distribution lists of establishments conducting recalls with State and Federal agencies with which the agency has negotiated memoranda of understanding. This new policy will allow

FSIS to better work with its partners throughout the Nation to more quickly and effectively carry out recalls of potentially contaminated product.

FISCAL YEAR 2004 BUDGET REQUEST

Now that I have provided a synopsis of FSIS' progress, I would like to present an overview of the fiscal year 2004 budget request for FSIS. The budget request for fiscal year 2004 would fund those programs previously discussed and will help FSIS reach the goal of becoming a world-class public health agency. By incorporating the principles of public health into all of our operations, we will be modernizing our inspection system to meet the goals and challenges of food safety in the 21st century. Implementation of these budget initiatives is imperative to helping us attain the public health vision we have set for FSIS. In fiscal year 2004, FSIS is requesting a program level of $899 million, a net increase of about $42 million over the enacted level for fiscal year 2003. Under current law, we are requesting an appropriation of $797 million and $102 million in existing user fees.

Supporting FSIS' Basic Mission

The FSIS budget request for fiscal year 2004 supports the agency's basic mission of providing continuous food safety inspection in each meat, poultry, and egg products establishment in the United States. The fiscal year 2004 budget includes $23.6 million in increases to cover pay and employee benefit costs, inflation, and the agency's support of State-inspection programs. The budget reflects the proposed fiscal year 2004 pay raise of 2.0 percent for Federal and State program personnel and the annualized cost of the 4.1 percent pay increase for 2003. These costs also include a total net increase of approximately $853,000 for state food safety and inspection. This includes Federal control of the Commonwealth of Virginia's inspection program beginning in July 2003, as well as the initiation of Maine's State inspection program.

New Initiatives

The fiscal year 2004 request includes a $19.3 million increase for new initiatives that support the Department's goals for FSIS. While the implementation of the HACCP system has provided a solid base for FSIS to carry out its goal of protecting the Nation's food supply, more can be done to strengthen this foundation. Thus, the fiscal year 2004 budget requests an increase of $5.7 million to enhance the agency's ability to train its workforce, which I mentioned earlier is my top priority. This will allow FSIS to re-tool and expand its existing training programs by incorporating a public health focus and integrating scientific and technical principles, including HACCP validation, with training on technical and regulatory approaches to inspection. In addition to increasing the technical skills of our employees, the agency intends to use training opportunities to strengthen the management capabilities of our workforce as well. Additionally, the agency plans to enhance training by taking the training opportunities we offer into the field. Employees would have a variety of training options, including the ability to take courses taught by university professors near their work sites.

The fiscal year 2004 budget includes an increase of $4.3 million to cover costs associated with funding 7,680 in-plant personnel in meat, poultry, and egg products plants. This is an increase of 80 slaughter inspectors and is necessary due to industry growth. The increase will allow the agency to ensure continuous inspection in each meat, poultry, and egg products establishment.

To achieve the agency's goal of applying science to all policy decisions, the fiscal year 2004 budget includes a new $1.7 million initiative to establish a continuous baseline program for risk assessments and performance measurement. While the agency has previously conducted baseline studies using its internal laboratory resources, this new initiative would include laboratory analyses using outside laboratories, would repeat each baseline study every 3 years to provide longitudinal data to track performance, and would provide scientific data needed for ongoing risk assessments. The use of nationwide microbiological baseline studies will improve data quality and help us further incorporate risk management into all regulatory and policy actions.

When a foodborne outbreak occurs, it is essential to identify the source of the outbreak so that the agency can take swift action to prevent further illnesses and warn the public of the product adulteration. Therefore, the fiscal year 2004 budget request includes $4.5 million to provide additional microbiologists, chemists, laboratory technicians, and other personnel to increase the agency's ability to identify adulterants in meat, poultry, and egg products. This funding will help the agency develop analytical methods to test food products for chemical, biological, and radiological contamination. This initiative will also increase sampling of ready-to-eat

products for the presence of bacteria such as Listeria monocytogenes and Salmonella. FSIS will increase sampling of these products from 10,000 to 15,000 annually and will add the capability to conduct 5,000 Listeria monocytogenes environmental samples annually. The agency also plans to increase sampling of raw ground beef and raw ground beef ingredients for E. coli O157:H7 from 7,000 to 15,000 samples annually.

As I mentioned earlier, education and outreach have always been important aspects of FSIS' mission and this is again reflected in the fiscal year 2004 budget request. The agency is requesting a $1.5 million increase to design a mass media campaign aimed at improving safe food handling practices of consumers at home. Emphasis will be placed on a program that communicates with under-served groups and uses mass media outlets to leverage limited education funding. Performance measures will be incorporated to evaluate the effectiveness of the campaign at spreading the food safety message.

It is important that foreign products meet U.S. standards. Therefore, the fiscal year 2004 budget request includes $1.8 million to increase FSIS equivalence reviews in exporting countries. In recent years, FSIS has experienced a rise in applications from foreign countries to export meat and poultry products to the United States. This funding is necessary for the agency to hire additional foreign auditors to meet the demands of increased foreign inspection system audits. This will help ensure that foreign meat, poultry, and egg products establishments are shipping product to the United States that meets the same standard of safety required in U.S. establishments.

User Fee Proposal

FSIS' fiscal year 2004 budget also includes a legislative proposal to recover the costs of providing inspection services beyond an approved 8-hour primary shift. FSIS collects $102 million in user fees annually to recover the costs of overtime, holiday, and voluntary inspection. If enacted, the level of appropriated funds needed would be reduced from $797 million to $675 million to reflect an increase in user fee funding of $122 million. This will result in savings for the American taxpayer.

CLOSING

Let me restate that we all have a role to play in improving public health. We will continue to hold ourselves and industry to a higher standard. This is not a pain-free process, but there will be tangible, and measurable, benefits for the American people. Our workforce has been reinvigorated by this challenge and we will deliver.

Mr. Chairman, this concludes my prepared statement. Thank you for the opportunity to submit testimony to the Subcommittee on how FSIS is working with Congress and other partners to become a first class public health agency. It is my hope that we can work together to make further improvements to our food safety system and continue to have the safest food supply in the world. I look forward to working with you to ensure that the vision of FSIS as a world-class public health agency is realized.

Senator BENNETT. Mr. Hawks

Mr. HAWKS. Thank you, Mr. Chairman, members of the Committee. It is a pleasure to be with you today to present the Marketing and Regulatory Programs' budget for 2004 [sic]. That budget represents the Animal and Plant Health Inspection Service, Agriculture Marketing Service, and Grain Inspection, Packers and Stockyards Administration. I am pleased to have with me today my deputy, Dr. Chuck Lambert. I have Kevin Shea representing the Administrator's Office from APHIS; Donna Reifschneider, the Administrator of Grain Inspection, Packers and Stockyards; and A.J. Yates, the Administrator of AMS.

We have a motto in MRP and that is "Working together works." In doing that, we have set several goals. The number one goal is to build broader bridges. When we say build broader bridges, we mean to help the outreach with the members of this committee, members of Congress, and our constituents to work through the issues that we have to deal with.

The next goal is to move more product. That one is pretty self-evident. And the next one is, invest in infrastructure. We feel that a healthy agriculture is an exportable and a saleable agriculture.

The next one is to grow our people. We feel that we must recruit, retain, and reward well-qualified people for our mission area within USDA as well as all of USDA.

The last goal is to sell agriculture as a profession. So we feel that that is very important, and I personally feel that agriculture is a great profession.

The budget that we have presented to you is approximately $1.2 billion. Three-hundred-and-eighty-two million dollars of that is funded by user fees. I will, in light of your request, this morning, deviate from my prepared remarks and address some of the issues that you had raised.

The actions that we have taken, the reaction to the finding of the BSE case in Canada, were immediate. I had an opportunity to do an opening session for the Office of International Epizootics in Paris on Sunday afternoon. We were there with the chief veterinary officers from around the world. We, I think, took appropriate action, immediate action. As you know, the borders were closed at 1:30 Eastern Daylight Time on Tuesday. We found out about the BSE case, the confirmed BSE case, earlier that morning.

We in APHIS are doing an extensive surveillance program. We had started that surveillance program last year. We tested 20,000 samples of the most likely candidates for BSE. That is actually over four times what the Office of International Epizootics recognizes as the standard.

So we feel that within APHIS, within USDA, we have a well-coordinated effort and are moving forward to address this situation, and I would concur with my colleagues and all of you here. We do have the safest food supply anywhere in the world and beef is what is for dinner tonight.

With the Grain Inspection, Packers and Stockyards, it is our intent to have fair and competitive trade in grain and poultry and meat. For Agriculture Marketing Service, it is our goal to help market more products and to find ways to improve the profitability of farmers.

PREPARED STATEMENTS

Mr. Chairman, in light of our time, I would like to close with that and say I would be happy to respond to any questions that this Committee has. Thank you, sir.

Senator BENNETT. Thank you.

[The statements follow:]

PREPARED STATEMENT OF WILLIAM T. HAWKS

Mr. Chairman and members of the Committee, I am pleased to appear before you to discuss the activities of the Marketing and Regulatory Programs of the U.S. Department of Agriculture and to present our fiscal year 2004 budget proposals for the Animal and Plant Health Inspection Service (APHIS), the Grain Inspection, Packers and Stockyards Administration (GIPSA), and the Agricultural Marketing Service (AMS).

With me today are Dr. Charles Lambert, Deputy Under Secretary for MRP; Mr. Bobby Acord, Administrator of APHIS; Mrs. Donna Reifschneider, Administrator of GIPSA, and Mr. A. J. Yates, Administrator of AMS. They have statements for the record and will answer questions regarding specific budget proposals.

Under my leadership, the Marketing and Regulatory Programs have addressed several broad goals and objectives which demonstrate that working together works.

Building Broader Bridges.—We strengthened cooperation and strategic partnerships with farmers and ranchers, States, foreign governments, congressional offices, agricultural commodity and industry associations, agricultural scientific groups, and other interested parties. We want to ensure that our policies and programs provide the most benefits they can to the affected people.

Moving More Product.—We expanded domestic and international market opportunities for U.S. agriculture products including value enhanced products and products of biotechnology. We have worked closely with the Foreign Agricultural Service and the U.S. Trade Representative to aggressively and creatively resolve sanitary, phytosanitary, biotechnology, grain inspection, commodity grading and other trading issues that limit our potential for growth in international trade.

Investing in Infrastructure.—We invested in stronger border security, pest and disease surveillance and monitoring, bricks and mortar such as the National Veterinary Science Lab in Ames, Iowa. We increased market news on export markets, made improvements in e-Government, enhanced investigations of anti-competitive market practices and provided greater support for biotechnology. Agriculture that is healthy, both biologically and economically, is a marketable agriculture.

Growing Our People.—We made a concerted effort to recruit, recognize and reward accomplishment and inspire current and future leaders within MRP. We are making MRP a place where the best and brightest want to be, including promising men and women in diverse fields such as journalism, accounting, and economics.

Selling Agriculture as a Profession.—We are creatively marketing the vital role that agriculture plays in every American's life to assist our efforts to recruit and retain the highest calibre workforce for MRP and USDA.

FUNDING SOURCES

The Marketing and Regulatory Program activities are funded by both the taxpayers and beneficiaries of program services. The budget proposes that they carry out programs costing $1.2 billion; with $382 million funded by user fees paid by the beneficiaries of the services.

On the appropriation side, under current law, the Animal and Plant Health Inspection Service is requesting $694.9 million for salaries and expenses and $5 million for repair and maintenance of buildings and facilities; the Grain Inspection, Packers and Stockyards Administration is requesting $41.7 million, and the Agricultural Marketing Service is requesting $102.9 million.

Legislation will be submitted, which if enacted would recover $36.5 million more in user fees. This legislation would authorize new license fees to recover the cost of administering the Packers and Stockyards (P&S) Act, additional license fees for facilities regulated under the Animal Welfare Act and additional grain inspection fees for developing grain standards. I will use the remainder of my time to highlight the major activities and their budget requests for the Marketing and Regulatory Programs.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

The fundamental mission of APHIS is to anticipate and respond to issues involving animal and plant health, conflicts with wildlife, environmental stewardship, and animal well-being. Together with their customers and stakeholders, APHIS promotes the health of animal and plant resources to facilitate their movement in the global marketplace and to ensure abundant agricultural products and services for U.S. customers. The APHIS mission satisfies five strategic goals. They include:

—Safeguarding plant and animal resources from foreign pests and diseases;
—Minimizing production losses and export market disruptions by quickly detecting and responding to outbreaks of agricultural pests and diseases;
—Minimizing risks to agricultural production, natural resources, and human health and safety by effectively managing pests and diseases and wildlife damages;
—Ensuring the humane care and treatment of animals; and
—Developing safe and effective scientific pest and disease control methods.

APHIS builds bridges by working in concert with its stakeholders—States, industry, and the public—to maintain and expand export market opportunities and to prevent the introduction and/or to respond to new threats of plant and animal pests and diseases. APHIS invests in the agricultural marketing infrastructure that helps protect the agricultural sector from pests and diseases while at the same time helping move more U.S. product.

APHIS' charge is a difficult one to meet and their excellence has been recognized. Progressive Farmer, one of America's best known agricultural publications, has always selected an individual as its "Person of the Year." This year, however, Progressive Farmer selected 8,700 of them—all the men and women of APHIS—to receive the 2003 People of the Year award. I am proud of their efforts, and appreciate the recognition bestowed upon them.

I would like to highlight some key aspects of the APHIS programs:

Homeland Security and Agricultural Border Protection.—Traditionally, APHIS' Agricultural Quarantine Inspection (AQI) program has had responsibility for excluding agricultural health threats. Annually, thousands of inspectors have inspected hundreds of thousands of cargo shipments and tens of millions of passengers' baggage arriving in the United States. They have intercepted tons of materials whose entry could jeopardize the agricultural sector. They have successfully excluded such threats as foot-and-mouth disease (FMD) and bovine spongiform encephalopathy (BSE), which could have devastated not only the agricultural sector, but other sectors of the economy as well.

That responsibility is now shared with the Department of Homeland Security (DHS). While most AQI staff are reassigned to the new Department, USDA retains the responsibility for promulgating regulations related to entry of passengers and commodities into the United States. We intend to work closely with our counterparts in DHS. USDA retains the direct role of ensuring that passengers and cargoes traveling from Hawaii and Puerto Rico comply with specified regulations to protect the health of the agricultural sector on the Mainland, including necessary quarantines. We retain responsibility for collecting the user fees and will be periodically reimbursing DHS for their inspection services.

Emergency Pest and Disease Programs.—The Administration is concerned about rising Federal costs of emergency pest and disease control activities, and the budget request assumes cost-sharing for such outbreaks. Cost-sharing levels are set by consideration of several factors applied to specific outbreaks. A proposed rule is expected to be published which will improve the Federal/cooperator partnership by establishing consistent criteria for determining Federal and non-Federal responsibilities, providing a more equitable and justifiable allocation of responsibility among all parties, and permitting State and local governments to better anticipate and plan for future needs. Without additional support on the part of cooperators in some programs, however, program operations could be reduced.

Moving More Product.—The Trade Issues Resolution and Management efforts are key to ensuring fair trade of all agricultural products. APHIS' staff negotiates sanitary and phytosanitary (SPS) standards, resolves SPS issues, and provides clarity on regulating imports and certifying exports which improves the infrastructure for a smoothly functioning market in international trade. Ensuring that the rules of trade are based on science helps open markets that have been closed by unsubstantiated SPS concerns. APHIS' efforts contributed to the opening or retention of $1.1 billion in export markets in fiscal year 2001 by helping resolve individual trade issues abroad. In 2002, APHIS resolved problems facing shipments of about $52 million of U.S. agricultural products held at ports of entry in foreign countries. This included about $16 million for fruit; $10 million for grain; $10 million for oilseeds and oilseed products; $5 million for animals and animal products; $4 million for cotton; $2 million for vegetables; and $5 million in other products.

Biotechnology.—Recent developments in biotechnology underscore the need for effective regulation to ensure protection of the environment and food supply, reduce market uncertainties, and to encourage development of a technology that holds great promise. APHIS has recently established a new Biotechnology Regulatory Services unit to consolidate and better coordinate our services and activities in this area. The new unit focuses on both plant-based biotechnology and transgenic arthropods. We also will be examining ways to regulate transgenic animals. By consolidating these activities into one unit, we will bring greater focus to our domestic and international policy coordination and development as well as our risk assessment, permitting, and compliance programs.

APHIS' 2004 BUDGET REQUEST

In a year of many pressing high-priority items for taxpayer dollars, the budget request proposes about $695 million for salaries and expenses. Notable shifts in budget priorities include:

A total of about $156 million for Foreign Pest and Disease Exclusion.—Efforts will be enhanced to exclude Classical Swine Fever from the United States and to improve our means of tracking animal and animal products entering and leaving the country. Decreases include those in Agricultural Quarantine Inspection activities

and, in keeping with cost-sharing provisions, reductions in fruit fly exclusion and detection activities.

A total of about $142 million for Plant and Animal Health Monitoring.—Experience gained from abroad about FMD and BSE highlights the need for rapid detection and response to agricultural health threats. Long-standing efforts have kept those diseases and others out of the United States, and vigilant surveillance and monitoring will still be done by APHIS. Increases would boost the availability of FMD vaccines from 19.5 million doses to 20.75 million doses, and support efforts to address increased incidence of smuggling and other threats from regulatory violations.

A total of $302 million for Pest and Disease Management Programs.—Once pests and disease are detected, prompt eradication reduces overall damages. In cases where eradication is not feasible (e.g., European gypsy moth), attempts are made to slow the advance, and damages, of the pest or disease. APHIS provides technical and financial support to help control or eradicate a variety of agricultural threats.

The budget includes a doubling of funding for efforts against chronic wasting disease, and other increases for low-pathogenic avian influenza and golden nematode activities. The budget also proposes a slight increase for wildlife services operations to enhance control over hazardous materials used in wildlife control activities.

Successes in boll weevil eradication and plum pox efforts allow some program reductions. The decrease stems from greater cost-sharing expected to be provided by cooperators and a 35 percent reduction in the estimate of planned program acres. Such cost-sharing would reduce Federal funding by about $32 million for efforts against Asian Longhorned Beetle, citrus canker, Mediterranean fruit fly (as mentioned above), plum pox virus, scrapie, and tuberculosis. However, the Federal Government would still pay over 50 percent of the cost of these programs.

A total of $15 million for the Animal Care Programs— APHIS will maintain its animal welfare and horse protection programs. The budget includes a proposal, similar to fiscal year 2003, to collect $7.8 million in additional fees charged to facilities and establishments required to be registered under the Animal Welfare Act but not currently subject to a fee. This includes research facilities, carriers, and in-transit handlers of animals.

A total of about $69 million for Scientific and Technical Services.—APHIS develops methods and provides diagnostic support to prevent, detect, control, and eradicate agricultural health threats, and to reduce wildlife damages (e.g., coyote predation). It also works to prevent worthless or harmful animal biologics from reaching consumers. The request would enhance biosecurity activities, the national animal health laboratory network, and physical security at select facilities.

Increased funds of $6.6 million for Biotechnology.—The budget includes a cross-cutting trade-related and biotechnology proposal in the Office of the Secretary. The Department anticipates a growing demand for trade negotiating efforts and biotechnology activities, including regulatory, market access and removal of trade barriers. Increased APHIS efforts related to biotechnology may be funded from these appropriations.

GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION

GIPSA's mission is to facilitate the marketing of livestock, meat, poultry, cereals, oilseeds, and related agricultural products and to promote fair and competitive trade for the benefit of consumers and American agriculture. It helps move more U.S. product both domestically and abroad by investing in domestic infrastructure that supports marketing within the grain and livestock industry. GIPSA fulfills this through both service and regulatory functions in two programs: the Packers and Stockyards Programs (P&SP) and the Federal Grain Inspection Service (FGIS).

Packers and Stockyards Programs. The strategic goal for the Packers and Stockyards Programs (P&SP) is to promote a fair, open and competitive marketing environment for the livestock, meat, and poultry industries. Currently, with 169 employees, P&SP monitors the livestock, meatpacking, and poultry industries, estimated by the Department of Commerce to have an annual wholesale value of over $115 billion. Legal specialists and economic, financial, marketing, and weighing experts work together to monitor emerging technology, evolving industry and market structural changes, and other issues affecting the livestock, meatpacking, and poultry industries that the Agency regulates.

We conducted over 1,400 investigations in fiscal year 2002 to enforce the Packers and Stockyards Act for livestock producers and poultry growers. More than 90 percent of identified violations were corrected (or issues resolved) within one year of the investigation's starting date.

The Swine Contract Library, mandated in the 2000 Appropriations Act, is in the final testing stage. The web-based computer system will be capable of receiving contracts, extracting unique contract provisions and posting summary information. GIPSA is making the necessary revisions to the final rule which would implement the Swine Contract Library. It is a sizable and complex undertaking to assure that the confidentiality requirements of the Act are maintained. For example, a single type of contract, received from less than 10 packers, can include more than 300 unique contract provisions to capture all of the ledger contracts priced off swine or pork market prices.

Federal Grain Inspection Service.—GIPSA(s Federal Grain Inspection Service (FGIS) facilitates the marketing of U.S. grain and related commodities under the authority of the U.S. Grain Standards Act (USGSA) and the Agricultural Marketing Act of 1946 (AMA). As an impartial, third-party in the market, we advance the orderly and efficient marketing and effective distribution of U.S. grain and other assigned commodities from the Nation's farms to domestic and international buyers. We are part of the infrastructure that undergirds the agricultural sector.

GIPSA created a long-term temporary assignment in Malaysia to assist the Southeast Asian agricultural attaches and cooperator organizations by providing technical assistance and education to customers of U.S. grain which would maintain and expand U.S. grain markets. This and other technical trade assistance, such as that provided to Mexico, facilitate the marketing of U.S. grain exports.

GIPSA works with government and scientific organizations to establish internationally recognized methods and performance criteria and standards to reduce the uncertainty associated with testing for the presence of biotechnology grains and oil seeds.

GIPSA received almost 3,000 comments on the advance notice of proposed rulemaking regarding how USDA can best facilitate the marketing of grains, oilseeds, fruits, vegetables, and nuts in today's evolving marketplace. A Process Verification Program is being considered for applying internationally-recognized quality management standards to verify that a biotech related quality control process has been used to produce a product rather than relying on end product testing. This would allow producers, marketers, suppliers, and processors to assure customers of their processes to provide consistent quality products.

Our efforts to improve and streamline our programs and services are paying off for our customers, both in terms of their bottom lines and in greater customer satisfaction. FGIS' service delivery costs (adjusted for inflation), decreased from $0.29 per metric ton in fiscal year 1998 to $0.26 per metric ton in fiscal year 2002. With the USDA export certificates that grain exporters received at this cost, exporters marketed over $15 billion worth of cereals and oilseeds. Likewise, here at home, buyers and handlers requested over 1.8 million domestic inspections that facilitated the trading of more than 131 million metric tons of cereals and oilseeds.

One indicator of the success of our outreach and educational initiatives is the number of foreign complaints lodged with FGIS regarding the quality or quantity of U.S. grain exports. In fiscal year 2002, FGIS received only 9 quality complaints and no quantity complaints from importers on grains inspected under the U.S. Grain Standards Act. These involved 197,423 metric tons, or about 0.2 percent by weight, of the total amount of grain exported during the year.

GIPSA'S 2004 BUDGET REQUEST

For 2004, the budget proposes a program level for salaries and expenses of $41.7 million. Of this amount, about $18.1 million is devoted to grain inspection activities for standardization, compliance, and methods development and approximately $23.5 million is for Packers and Stockyards Programs. The 2004 budget includes:

An increase of about $1 million to implement a new Pilot Audit Program.—The P&SP has never audited a large packer. As a pilot, this initiative would audit the top four steer and heifer meatpackers who handle 80 percent of the slaughter. The audits are anticipated to result in substantially better understanding of their financial operations to the regulated industry and lead to better financial protection of producers.

An increase of $500,000 to enhance compliance and review the Packers and Stockyards Act.—Efforts will respond to a GAO recommendation to provide industry participants with clarification of GIPSA's views on competitive activities. Further, given changes in the livestock sector, the P&SP is preparing to undertake a complete review of the Packers and Stockyards Act and its regulations. These activities may result in a future increase in the number of investigations conducted and monies recovered or returned to the regulated industries. Biotechnology Funds. Some of the $6.6 million requested to support crosscutting trade and biotechnology activities in

the Office of the Secretary may be applied to GIPSA's trade and biotechnology efforts.

New User fees.—New user fees, similar to those proposed for fiscal year 2003, would be charged to recover the costs of developing, reviewing, and maintaining official U.S. grain standards used by the grain industry. Those who receive, ship, store, or process grain would be charged fees estimated to total about $5 million to cover these costs. Also, the Packers and Stockyards program would be funded by new license fees of about $24 million that would be required of packers, live poultry dealers, stockyard owners, market agencies and dealers, as defined under the Packers and Stockyards Act.

AGRICULTURAL MARKETING SERVICE

The mission of AMS is to facilitate the marketing of agricultural products in the domestic and international marketplace, ensure fair trading practices, and promote a competitive and efficient marketplace to the benefit of producers, traders, and consumers of U.S. food and fiber products. We accomplish this mission through a variety of voluntary fee-based services and publicly funded activities that help our customers find ways to better market food and fiber products and improve their profitability.

AMS continually monitors the needs of the agricultural industry, develops strong partnerships with cooperating State agencies, and identifies new technology that can be used to improve their effectiveness. AMS depends on strong cooperative partnerships with State programs and other Federal agencies to facilitate the collection and dissemination of information, provide inspections, and otherwise maximize the value of State and Federal programs by sharing and coordinating the use of available resources. Through increased cooperation, AMS has been able to achieve a number of programmatic goals.

Global Agricultural Marketing.—AMS offers a range of services that give sellers of agricultural products a competitive advantage in the global marketplace. In 2002, AMS initiated the Global Market Expansion program to strengthen the support of export marketing for U.S. agricultural products. Under this activity, AMS experts served on, and in several cases headed, U.S. delegations to meetings of international food and fiber standards-setting organizations. AMS also provided technical expertise to the U.S. trade officials in negotiations on international standards. As an example of the critical role AMS plays in the development of international standards, AMS provided the technical support necessary to dissuade China from adopting cotton standards that lack recognized measurement technologies and could have posed a barrier to U.S. cotton exports. AMS also led the development of lamb and poultry quality standards that will serve as models for government and industry throughout Europe. Through such participation, AMS is able to influence the design of food quality standards and model inspection protocols so that they are fair to U.S. shippers and they do not become barriers to U.S. agricultural trade. In 2004, AMS will continue to do its part in helping to reduce trade barriers relating to commodity standards and product testing by serving as delegates and by leading international committees and organizations.

Science and Technology Programs.—Through cooperative relationships with the States, AMS is in a unique position to effectively and efficiently develop scientific data that is needed to support domestic and export marketing of U.S. food products. The Pesticide Data Program (PDP) is a unique and valuable source of statistically valid data on pesticide residues in food and water. The program provides information to the Environmental Protection Agency that is vital for realistic assessments of dietary risk from pesticides on food commodities available in the marketplace. PDP is instrumental in providing data that addresses domestic and international public concerns about the effects of agricultural pesticides on human health and environmental quality. Exporters use PDP data to verify for foreign governments and buyers that U.S. agricultural commodities are safe for consumption. Importantly, PDP is built on Federal-State partnerships with 10 States—California, Colorado, Florida, Maryland, Michigan, New York, Ohio, Texas, Washington and Wisconsin. These States collect and test commodities for pesticide residues.

AMS' experience with PDP provided the foundation for initiating the Microbiological Data Program. MDP is designed to gather baseline data to assess the risks of microbial contamination of fruits and vegetables, if any. Using the PDP programmatic framework, AMS collects information regarding the incidence, number and species of foodborne pathogens and indicator organisms on domestic and imported fresh fruits and vegetables. In fiscal year 2002, AMS worked with cooperating States and interested industry parties to initiate microbiological data collection and testing. AMS developed operating procedures with FDA, the Centers for

Disease Control and Prevention, and State laboratories. During 10 months of sample testing, approximately 19,000 analyses were performed on 9,400 samples. The first report will be published this year with calendar year 2002 data. The data will be provided to public health agencies and the food industry for decision-making and evaluation of procedures intended to reduce or eliminate harmful microorganisms from foods.

National Organic Certification Program.—On October 21, 2002, the Secretary launched the implementation of AMS' National Organic Standards Program, which for the first time provides consistent labeling of agricultural products coast to coast. The organic standards were developed with extensive industry input and hundreds of thousands of public comments. Thanks to this effort, any organic agricultural product must meet USDA standards in order to be sold as "organic." Today, consumers know the exact organic content of the food they buy. Consumers can tell organically produced food from conventionally produced food by looking at package labels and watching for signs in the supermarket.

On August 23, 2002, AMS announced that Federal funds appropriated in the Agriculture Risk Protection Act of 2000 and those made available by the Farm Bill were available to defray the cost of organic certification. AMS has entered into cooperative agreements with 45 States to distribute the funds. The remaining 5 States do not charge fees for organic certification and are not eligible for cost-sharing funds.

As directed by the Farm Bill, AMS is drafting a report to Congress on the availability of key inputs into organic production, including the availability of organically produced feedstuffs for the organic production of livestock. AMS has contracted with Iowa State University to survey grain producers and dealers in Midwestern States to ascertain planting and harvesting intentions for the years 2002–2004. This report should be completed this spring.

Country of Origin Labeling.—The 2002 Farm Bill requires USDA to issue country of origin labeling guidelines for use by retailers who wish to voluntarily notify their customers of the country of origin of beef, lamb, pork, fish, perishable agricultural commodities, and peanuts. AMS published the guidelines for voluntary country of origin labeling in October 2002 and is collecting comments on their utility through April of this year. We have already conducted six of the twelve listening sessions held throughout the country regarding the implementation of these guidelines. After these comments are evaluated, the program will begin developing the mandatory requirements, which are to be published by September 30, 2004.

AMS' 2004 BUDGET REQUEST

For AMS, the budget proposes a program level of $297 million, of which over 65 percent will be funded through user fees. The budget requests an appropriation of $76 million for Marketing Services and Payments to States, including increased funding for paycosts, in order to maintain existing program operations. The budget includes a request for $26.4 million in Section 32, including increases for paycosts, associated with administering marketing agreements and orders and commodity procurement programs.

CONCLUSION

This concludes my statement. I am looking forward to working with the Committee on the 2004 budget for the Marketing and Regulatory Programs. We believe the proposed funding amounts and sources of funding are vital to protecting American agriculture from pests and diseases and for moving more product to foreign markets. It will provide the level of service expected by our customers—the farmers and ranchers, the agricultural marketing industry, and consumers. We are happy to answer any questions.

PREPARED STATEMENT OF BOBBY R. ACORD, ADMINISTRATOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Mr. Chairman and members of the Subcommittee, it is indeed a pleasure for me to represent the Animal and Plant Health Inspection Service (APHIS) before you today. Since appearing before you last year, APHIS continued its vigilant effort to prevent foreign agricultural pests and diseases from entering the United States. We also heightened our efforts to keep American agricultural products moving overseas. It is in the context of these two broad objectives that I want to report on our fiscal year 2002 highlights, and our fiscal year 2004 budget request.

APHIS' mission has been constantly evolving—right along with the evolution of food production and marketing practices of the past 100 plus years and the Federal

government's involvement in protecting and serving U.S. agriculture. APHIS currently relies on a set of interlocking protection strategies to meet the expectations of its traditional agricultural stakeholders and to ensure that it has the capacity to address the needs of non-agricultural stakeholders. These strategies enable us to achieve our two main goals—to safeguard the health of animals, plants, and ecosystems in the United States and to facilitate safe agricultural trade. Hence our mission—To protect the health and value of America's agricultural and natural resources.

SAFEGUARDING THE HEALTH OF AMERICA'S AGRICULTURAL AND NATURAL RESOURCES

American Agriculture can produce abundantly and export food and fiber to the rest of the world only if it is healthy and free of the many pests and diseases that plague most of the world. Other countries will accept our exports only if the products are believed to be free of pests and diseases. It is APHIS' responsibility to provide leadership in agricultural health. There are five components in this first goal of our mission. The first component is to keep foreign pests and diseases far away from the U.S. border.

Conduct Offshore Threat Assessment and Risk Reduction. APHIS is building bridges with foreign countries to prevent the import of pests and diseases by allowing only healthy plants and animals and related products to the United States. APHIS' staff is a vital link between U.S. markets and foreign businesses that want to trade in these commodities.

Our Foreign Animal Diseases (FAD) and Foot-and-Mouth Disease (FMD) program works to detect and control outbreaks of animal diseases in foreign countries, again far from our shores. APHIS' key strategy to prevent the movement of FMD northward from South America is to maintain an FMD-free area along the Colombia-Panama border. Our efforts have effectively prevented a reintroduction of FMD into Mexico and the United States. That Central America has never had an outbreak of FMD demonstrates the effectiveness of the prevention activities throughout the region. Also, the FAD program has been expanding to address additional geographical areas and diseases. For example, animal health experts have been stationed in China and southern Africa to address potential threats from those regions.

Our Fruit Fly Exclusion and Detection program is working towards establishing and maintaining a fly-free barrier in Central America to prevent the spread of Medfly into the United States. In 1999, program personnel quickly and effectively responded to an emergency situation in Mexico that could have resulted in the establishment of Medfly in the United States by 2005. Since then, APHIS has been working in cooperation with Mexico and Guatemala to carry out Medfly eradication and control activities in those countries to prevent the spread of Medfly through Mexico into the United States. The economic significance of keeping this foreign pest at bay is apparent from the costs that could result from the establishment of Medfly into the United States. For example, the total cost to Florida's agricultural producers if Medfly were to become established in that state could total $33 million annually.

We continue significant progress towards protecting the United States from overland transmission of screwworm, a parasite that produces flesh-eating larvae. Screwworm infestations decrease the value of and can eventually even kill livestock. The Screwworm program consists of cooperative programs with Mexico, countries of Central America, and Panama. The goal of eradicating the pest to the Darien Gap in Panama is nearly complete, and the time has come to establish a permanent barrier against the pest. Once the barrier is in place, U.S. livestock producers will be securely protected against this costly pest.

APHIS works closely with foreign countries to set up preclearance programs. These preclearance programs facilitate the smooth trade of agricultural products to U.S. markets and ensure that the products are pest- and disease-free before they touch U.S. shores. One of the most successful of these preclearance programs is in Holland, where APHIS officials have been inspecting tulips, daffodils, and other flower bulbs since 1951. In Chile, APHIS has been inspecting all fruits and vegetables destined for U.S. consumers since 1981.

APHIS is participating in the first passenger pre-departure inspection program with a foreign government in the Dominican Republic to mitigate the risk of Classical Swine Fever. Working with the government of the Dominican Republic, APHIS inspects air and ferry passengers destined for the United States mainland and Puerto Rico to ensure they are not carrying prohibited plant and animal products or animal byproducts. So far, the program has been an effective means of protecting the multi-billion dollar U.S. pork industry. By performing inspections off shore, we reduce the chance of the disease being brought to the United States mainland.

In our Tropical Bont Tick program, APHIS employees are preventing the introduction of heartwater and increased levels of dermatophilosis into the livestock industry and wildlife populations of the United States from Caribbean islands infested with tropical bont ticks. The cooperative program has eradicated ticks from 6 of the 9 islands involved so far, towards a goal of eradicating this pest from the Western Hemisphere.

Regulate and monitor to reduce the risk of introduction of exotic invasive species While our first component includes offshore activities, the second component requires vigilant monitoring efforts at first points of entry into the United States. We must have intensive searches and aggressively enforce our regulations.

To reduce the threat of agricultural pests and diseases reaching the mainland United States, APHIS screens passengers and passenger baggage in Hawaii and Puerto Rico prior to departure. In fiscal year 2002, APHIS inspected over 1.5 million passengers before their departures from Hawaii and Puerto Rico. Again, by inspecting passengers offshore, we reduce the chance of them bringing pests or disease from those areas. In addition, passenger preclearance programs exist in Canada, the Bahamas, Bermuda, and Aruba. Program activities include inspecting aircraft and passenger baggage for prohibited agricultural products and ensuring passengers and crew departing from these foreign locations are in compliance with our regulatory requirements. APHIS works in coordination with the other U.S. Federal Inspection Service (FIS) Agencies—Customs and Immigration—to insure all passengers are in compliance with the U.S., FIS laws and regulations at these locations. Because these passengers go through the thorough FIS inspection, they arrive in the United States at a domestic terminal; they are not subject to FIS inspectional activities upon arrival. Operations of these programs were transferred to the Department of Homeland Security, along with other FIS components. APHIS also cooperates with the U.S. Department of Defense in inspecting military passengers and equipment prior to their returning from overseas. During fiscal year 2002, the military preclearance program expanded to include personnel stationed overseas in Afghanistan and Uzbekistan as part of Operation Enduring Freedom. In total, APHIS inspectors cleared over 9 million passengers en route to the United States.

Part of APHIS' strategy is to respond to threats of intentional introduction of illegal products. We have increased the capacity of the Smuggling Interdiction and Trade Compliance (SITC) staff and field personnel. The staff analyzes pathways, prosecutes smugglers, and provides outreach to increase industry compliance with our regulatory requirements. APHIS personnel have worked closely with other Federal agencies and local cooperators, focusing specifically on the illegal movement of agricultural plant and animal products into the United States. SITC began expanding their activities in fiscal year 2001 to respond to the spread of foot-and-mouth disease worldwide.

The program used supplemental funding in fiscal year 2002 to further increase staffing and apply new methods towards smuggling reduction. APHIS seized nearly 2.7 million prohibited plant and animal products, at markets, warehouses, and ports of entry. When we detect a prohibited item, we identify the item's origin and the responsible shippers, importers, and broker. By maintaining relevant information in databases, the program can target specific commodities and importers. SITC also worked with private industry on five national recalls of prohibited commodities, including South African and Argentine lemons and Mexican lemon grass and mangoes.

APHIS, through its Animal and Plant Health Regulatory Enforcement program ensures uniform compliance with Federal laws and regulations through a combination of sound enforcement and strong educational efforts. We investigate violations, collect evidence, issue and collect civil penalties, and develop alleged violation cases for formal prosecution.

APHIS continues to work to improve the timeliness and quality of investigations despite a continuing increase in the number and scope of violations. APHIS personnel conducted 927 investigations involving plant quarantine violations in fiscal year 2002 resulting in 139 warnings, 363 civil penalty stipulations, 21 Administrative Law Judge decisions, and approximately $508,000 in fines. APHIS also conducted widespread market surveillance activity to intercept prohibited foreign fruits and vegetables illegally smuggled into the United States. Significant cases involved the illegal importation of Mexican avocados into the United States and tracing the distribution of Spanish Clementine oranges infested with Mediterranean fruit fly.

We conducted 413 investigations involving animal health programs in fiscal year 2002, resulting in 114 warnings, 34 civil penalty stipulations, 9 Administrative Law Judge decisions, and approximately $46,000 in fines. In addition, APHIS took several hundred administrative actions on animal health program violations disclosed at the border ports by agricultural quarantine inspectors. The alleged violations

were concentrated in veterinary accreditation, animal identification, brucellosis, pseudorabies, and import/export programs. We provided significant enforcement support during the Avian Influenza eradication effort in Virginia poultry and at New York live bird markets.

Using supplemental funds, APHIS hired additional investigators to address the growing threats to our nation's agriculture and food supply from bioterrorism threats, illegal activities such as smuggling, and violations of the Swine Health Protection Act, principally in Puerto Rico, Arkansas, Hawaii, and Florida. Violations of the Act can have huge ramifications—foreign officials identified illegal practices associated with prohibited feeding of garbage to swine as the source of the devastating Foot-and-Mouth Disease outbreak in the United Kingdom in fiscal year 2001.

Ensure safe research, release, and movement of agricultural biotechnology events, veterinary biologics, and other organisms The third component of our safeguarding goal addresses the rapidly moving advances in laboratory practices and biotechnology. The United States leads the world in the safe development and commercialization of biotechnology-derived crops. Along with the Environmental Protection Agency and the Food and Drug Administration, APHIS works to ensure that these products will not harm agriculture, the environment, or human health. Specifically, APHIS regulates the movement, importation, and field testing of bioengineered plants and microorganisms through permitting to ensure that field testing of transgenic plants does not lead to unwanted environmental effects.

APHIS has recently established a new biotechnology unit and is proposing a shift in the program line item structure to consolidate and better coordinate our services and activities in this area. The new unit and program line item, Biotechnology Regulatory Services, is responsible for programs focusing on both plant-based biotechnology and transgenic arthropods. We also will be examining ways to regulate transgenic animals. By consolidating these activities into one unit, we will bring greater focus to our domestic and international policy coordination and development and our risk assessment, permitting, and compliance programs.

Our Veterinary Biologics program works to provide pure, safe, potent, and effective veterinary biological products in the United States. Program activities include licensing veterinary biological products, inspecting licensed manufacturing facilities, testing statistically based samplings of licensed products, and issuing permits for product importation. In fiscal year 2002, APHIS issued 106 product licenses. Veterinarians and animal owners now have 19 new products for the diagnosis, prevention, or treatment of animal diseases. The Agency also terminated 76 product licenses for obsolete products.

APHIS provided oversight to over 2,512 active licensed or permitted products for the control of 196 animal diseases in fiscal year 2002. APHIS approved 16,796 serials of veterinary biologics in fiscal year 2002, while rejecting 28 serials for failing to meet Agency requirements. The Agency conducted 831 tests on 228 of the 12,059 serials eligible for testing. APHIS performed 58 regulatory actions and 28 investigations of possible regulation violations. APHIS shipped 4,272 vials of reagents to facilitate testing consistency and quality by biologics manufacturers and other regulatory authorities. In addition, APHIS developed 4 new reagents.

In APHIS' Plant Methods Development Laboratories program, the Center for Plant Health Science and Technology provides advanced scientific and technological capabilities to protect and improve our nation's agriculture and public health. Methods development supports APHIS programs by optimizing existing pest management practices and by developing new technologies for pest exclusion, detection, survey, and management. We accomplish this by evaluating biocontrol organisms, evaluating new biological and chemical materials, adapting or inventing equipment, providing technical consultation and training, collecting and disseminating pertinent information, participating in strategic and tactical planning, serving as a liaison with the research community, and integrating technological advancements into integrated pest management systems. This system maintains both rapid response and long range capabilities for serving APHIS and stakeholders.

Manage issues related to the health of U.S. animal and plant resources and conflicts with wildlife. The fourth safeguarding component involves diligent control and eradication efforts relating to pest, disease, and wildlife conflicts that already exist in the United States. In cooperation with the States, APHIS works to improve the general health of our Nation's multi-billion dollar agriculture industry through management techniques designed to eradicate harmful pests and diseases, or, if eradication is not feasible, minimize their economic impact. We monitor endemic diseases and pests through surveys to detect their location and through inspections aimed at preventing their spread into noninfested parts of the country. We also monitor and enforce compliance with requirements of the Animal Welfare Act and the Horse Protection Act.

The Boll Weevil Eradication Program (BWEP)—which has been a model of cooperation between Federal and State regulatory officials, extension and research personnel, and cotton producers—continued reducing and ultimately eliminating losses caused by the boll weevil. This program's fiscal year 2002 performance target was 7 million cumulative weevil-free acres of the 16 million acres of U.S. cotton produced. The actual number of weevil-free acres in fiscal year 2002 was 6.5 million. This result was attributable to a slight reduction in acres planted and interruptions in aerial treatments resulting from the events of September 11, 2001. The 6.5 million acres are in the program's post-eradication phase, while 9.2 million acres are in the active phase, and the remaining 300,000 acres are expected to join the BWEP by fiscal year 2005.

The cooperative pink bollworm exclusion program continued protecting 700,000 cotton acres in the San Joaquin Valley of California through extensive surveys and preventative sterile moth releases. As a result of the efforts of local growers and APHIS personnel, no new infestations have been found outside the regulated area since fiscal year 2000. APHIS is continuing to work with collaborators in universities, industry, and the Agricultural Research Service to refine a biologically based pink bollworm eradication system. In addition, APHIS began a cooperative area-wide Pink Bollworm/Boll Weevil Eradication Program with growers, State, and Federal cooperators in parts of New Mexico, Texas, and northern Mexico, where the pests are still present.

The State-Federal Cooperative Brucellosis Program works to eradicate Brucella abortus from the bovine population and Brucella suis from the swine population of the United States. This program protects the cattle and swine industries. In fiscal year 2002, the National Brucellosis Eradication Program continued to center around finding and eliminating the last vestiges of brucellosis in the United States. The program increased emphasis on surveillance and the testing of adjacent, contact, and community herds. There were 9 affected cattle herds disclosed in fiscal year 2002, compared to 6 in fiscal year 2001, and 14 in fiscal year 2000. The nine affected herds were in Texas, Missouri, South Dakota, Oklahoma, and Idaho.

We also continued the Accelerated Pseudorabies Eradication Program, Scrapie Flock Certification Program, and Bovine Tuberculosis Eradication Program, among other animal health programs.

Before I move on to describe our Wildlife Services program, let me emphasize how important APHIS' relationships are with our State and Tribal partners in conducting these eradication and control programs. Federal-State-Tribal cooperation is essential for these types of programs to succeed, in addition to the support we receive from academia and industry.

APHIS' Wildlife Services (WS) operation provides Federal leadership in managing wildlife conflict. Part of the program's mainstay is protecting American agricultural resources. In fiscal year 2002, APHIS carried out various activities related to Bovine Tuberculosis (TB) in wildlife populations. We began a pilot project providing fencing around feed storage areas on farms to prevent the transmission of bovine TB between cattle and deer. The goal of the pilot project is to determine fencing designs that are both effective and practical. Additionally we recorded observations of wildlife patterns on many of the bovine TB positive farms to determine what activities may contribute to transmission.

Protecting human health and safety also is a part of APHIS/WS operations. APHIS assisted the Colorado Division of Wildlife and the Wisconsin Department of Natural Resources with surveillance and disease management strategies to reduce the prevalence of Chronic Wasting Disease (CWD) in wild cervid populations. APHIS worked closely with State wildlife agencies, the U.S. Fish and Wildlife Service, and local governments in addressing increased problems with non-migratory, resident Canada geese in fiscal year 2002. With the current population exceeding 2 million geese and increasing exponentially, this growing bird population is a primary concern in the eastern and the central United States and increasing in the west. Problems include threats to public safety at airports and air bases, contamination of water supplies and recreational beaches, and damage to lawns, turf areas, and agricultural resources such as seed production.

To protect both humans and livestock, APHIS/WS also continued an oral rabies vaccination (ORV) program. The goal of this program is to establish and maintain immunization barriers to contain specific strains of rabies in wildlife populations. To stop the spread of raccoon rabies westward, APHIS extended an older ORV barrier in the northeastern States and Ohio into West Virginia, through western Virginia, and into eastern Tennessee. Program officials also continued to distribute ORV baits in the Northeast. To stop the disease's spread in coyotes and gray foxes in Texas, program officials also continued the ORV program in that state.

APHIS also works to protect natural resources and property. In Maryland, APHIS is cooperating with several governmental and private partners in managing nutria. Nutria are non-native to North America and are impacting sensitive marshes of the Chesapeake Bay. APHIS continues to cooperate with various State and Federal agencies to protect reintroduced black-footed ferrets from predators and to monitor for diseases that may impact ferrets in Montana, Wyoming, Colorado, and other States where they have been reintroduced. The Agency's beaver damage management activities in Alabama, Florida, Georgia, Kentucky, Louisiana, Maine, Mississippi, North Carolina, South Carolina, Tennessee, Wisconsin, and Virginia throughout fiscal year 2002 averted impending beaver damage to forest and agricultural resources, waterways, and highway infrastructures. Humans and wildlife continue to compete for habitat as both populations increase. In fiscal year 2002, APHIS provided technical assistance to approximately 60,000 individuals in urban and suburban areas concerned with wildlife damage to property; we now have a 1–800 Nuisance Wildlife Hotline services in cooperation with State Agencies in four States.

APHIS' Wildlife Services (WS) Methods Development program conducts programs to develop new or improved methods for reducing wildlife/agriculture conflicts. The National Wildlife Research Center (NWRC) of APHIS' Wildlife Services program provides scientific information for the development and implementation of effective, practical, and socially acceptable methods for wildlife damage management. This helps ensure that high-quality technical and scientific information on wildlife damage management is available for the protection of crops, livestock, natural resources, property, and public health and safety.

WS methods development activities include methods to manage and resolve wildlife disease impacts on agriculture and methods to reduce invasive species damage to agriculture and natural resources. For example, the program has developed methods to mitigate blackbird damage to sunflowers and rice, methods to reduce bird hazards to aviation, techniques to control mountain beaver and bear damage to western forests, methods to reduce rat damage to sugarcane and macadamia nuts, methods for reducing cormorant depredation at aquaculture facilities; and approaches to reduce coyote damage to livestock. APHIS develops analytical chemistry methodology to support the registration and re-registration of chemicals for small mammals, for bird and predator control, and for the identification of potential repellents to support non-lethal wildlife damage management control strategies. During fiscal year 2002, approximately 75 percent of WS methods development resources went toward non-lethal approaches to wildlife damage management.

APHIS' Animal Welfare program continues to focus its resources on conducting quality inspections under the Animal Welfare Act at USDA licensed and registered facilities. The use of the program's risk-based inspection system concentrates activities on facilities where animal welfare concerns are the greatest. With the funding increase in fiscal year 2002, APHIS hired 16 new animal care inspectors who, by the end of the fiscal year, were being trained and had started to conduct inspections. As a result, the number of inspections increased by 1 percent, continuing the upward trend in inspections that began in fiscal year 2001, following a sustained period of decline throughout the 1990s. By the end of fiscal year 2002, the number of animal care inspectors stood at 98, an increase of 53 percent from the low of 64 at the end of fiscal year 1998.

In the Horse Protection program, APHIS has been working for nearly a decade with Horse Industry Organizations (HIOs) certified under the Horse Protection Act to develop a partnership whereby the HIOs can assume greater responsibility for self-regulation. The current plan began with the 2001 horse show season and ends in December 2003. APHIS plans to continue offering the plan in fiscal year 2003, possibly with some modifications, for those HIOs wishing to use it.

Respond to emergencies and emerging issues—surveillance, quick detection, containment, and eradication. The fifth component of APHIS' safeguarding system requires that we move quickly when an outbreak or other emergency situation does occur. Quick action will help safeguard other resources and will reduce adverse trade implications for our products. APHIS' Emergency Management System (EMS) is a joint Federal-State-industry effort to improve the ability of the United States to deal successfully with animal health emergencies, ranging from natural disasters to introductions of foreign animal diseases. In addition to unintentional introductions of foreign animal diseases, the EMS addresses intentional introductions and emerging diseases that could pose a threat to animal agriculture. With full readiness to deal with animal health outbreaks, we can reduce the threat of the outbreak on the Nation's food supply and economic well-being. While APHIS conducts the majority of its work related to animal emergency management within this program, ac-

tivities such as foreign animal disease investigations and training are funded within the animal health monitoring and surveillance program.

In fiscal year 2002, APHIS developed and participated in many State-level test exercises to increase the confidence and capability of the first responders to an animal health emergency in the United States. APHIS also participated in the development and implementation of an international animal health test exercise in Australia.

In addition, APHIS initiated the distribution of $18.5 million in Homeland Security Supplemental funds to States and Tribal Nations to help bolster their emergency preparedness and surveillance efforts. Of this, $11 million went to States and Tribal Nations to enhance emergency preparedness efforts, $4.5 million went to States to enhance animal health surveillance, and $3 million is going toward the purchase of carcass disposal systems for three States: California, Wisconsin, and Texas.

Through the Pest Detection program, APHIS and the States participate in the Cooperative Agricultural Pests Survey (CAPS) program, which provides the domestic infrastructure necessary for early detection of plant pests and weeds that enter into the United States or expand into new areas. Survey targets include weeds, plant diseases, insects, nematodes, and other invertebrate organisms. Program activities include evaluating pest risks, conducting detection surveys, responding to detections in a timely manner, collecting and reporting data, developing State Pest Lists, assessing risk and analyzing pathways, and communicating with the public.

Using funds provided in the fiscal year 2002 Homeland Security Supplemental appropriation, APHIS has begun efforts to significantly strengthen our pest detection capabilities. We are in the process of hiring 26 personnel trained in pest detection technologies at key U.S. locations to coordinate and oversee early detection surveys in cooperation with the States. In addition, we obligated $4 million in fiscal year 2002 to expand cooperative agreements for implementation of the CAPS surveys within all the States. We have also begun to train identifiers and procure up-to-date surveillance equipment to ensure that data are of high quality and standardized across the country. This equipment will also allow us to conduct research to develop better survey tools and techniques and undertake pathway analyses to facilitate interception. We obligated an additional $4.5 million from the Homeland Security supplemental appropriation for fiscal year 2003 CAPS agreements to sustain these efforts. The States are using this money to build survey infrastructure. These activities include hiring survey coordinators and purchasing equipment.

APHIS' Animal Health Monitoring and Surveillance program maintains a cadre of trained professionals to quickly detect potential animal health emergencies. APHIS continually evaluates its means and methods for safeguarding American agriculture from foreign animal disease, such as bovine spongiform encephalopathy (BSE). To date, no case of BSE has ever been detected in the United States although more than 46,475 samples have been tested. This program also surveys for poultry, miscellaneous equine, and other animal diseases.

Through early detection and rapid response programs, APHIS is prepared to respond immediately to potential animal and plant health emergencies. In fiscal year 2002, APHIS took quick action on the following plant and animal situations: Asian Longhorned Beetle, Low Pathogenic Avian Influenza, Chronic Wasting Disease, Citrus Canker, Classical Swine Fever, Infectious Salmon Anemia, Karnal Bunt, Mediterranean Fruit Fly, Pierce's Disease/Glassy-winged Sharpshooter, Rabies, and Scrapie. The Secretary used her authority to transfer in 2002 over $200 million to battle these pests and diseases. Without the quick detection and early, rapid response, the cost to control the outbreak would have undoubtedly been higher. As of May 2, 2003, the Secretary has transferred over $276.67 million to quickly detect, control the spread of, and eliminate pests and diseases such as tuberculosis, exotic Newcastle disease, Mediterranean fruit fly, chronic wasting disease, and Glassy-winged Sharpshooter, Spring Viremia of Carp, and Emerald Ash Borer.

Facilitate Safe Agricultural Trade

The second goal in our mission is to facilitate agricultural trade. The key to assuring trading partners of the health of our products is a credible system to assess American agriculture and document that it is healthy and that other countries have nothing to fear from our exports. This is the first component in facilitating trade. We must also certify the health of our agricultural exports, resolve trade barriers, and provide expertise and training in animal and plant health.

Document the health status of U.S. agriculture and related ecosystems. The World Trade Organization and the North American Free Trade Agreement commit countries to recognizing disease- and pest-free areas within a country even if a particular pest or disease exists elsewhere in the nation. This concept of regionalization is

founded on the long-standing idea that import requirements should be based on geography and science rather than on politics.

APHIS' Pest Detection program provides documentation of our pest status in plant resources. Examples of observations include taking grain samples for Karnal bunt, setting traps for fruit flies, or checking trees for citrus canker and plum pox. A "negative" observation is registered when we do not find the plant pest; a "positive" observation is recorded when we do. Both positive and negative results yield valuable and useful information for trade discussions, as can be seen with Leek moth, which affects onions and garlic. We continue to show that the United States does not have this pest based on continuing negative survey results.

We also conduct delimiting surveys for plant pests that have invaded the United States and may be expanding their range. These include apple ermine moth, cereal leaf beetle, citrus leaf miner, pine shoot beetle, and several other bark beetles. The program manages data for other species including gypsy moth, imported fire ant, Mediterranean fruit fly, pink bollworm, giant Salvinia, golden nematode, and other regulated, cooperative program pests. Surveys for these pests also assist in the export of U.S. agricultural commodities.

APHIS continued using the CAPS network to conduct the Karnal Bunt (KB) National Survey in response to the 1996 detection of the disease in Arizona and the 2000 detection in northern Texas. By collecting extensive survey data demonstrating the limited distribution of KB in the United States, APHIS provides assurance to all trade partners that KB is not present in major wheat-producing areas of the United States, thereby insuring annual agricultural exports of up to $3.5 billion. Plum pox is another project in which the collection of national data has helped to keep budwood markets open by showing the absence of the pest from various areas around the United States.

The Agency's proactive National Animal Health Monitoring and Surveillance (NAHMS) program produced and interpreted scientifically valid information for policy makers, producers, and consumers. NAHMS delivered objective information addressing animal health as it pertains to U.S. trade, agricultural productivity, public health, and on-farm quality assurance. Collaborative information sharing and producer confidentiality are cornerstones of the program. Through effective partnerships with animal commodity producer groups, State governments, university researchers, and other Federal agencies, the program met producers' and the U.S. public's information demands in a cost-effective, collaborative manner while minimizing duplication of effort.

Certify the health of animals and plants and related products for export and interstate commerce APHIS' Import/Export program regulates the importation of animals and animal products and promotes markets abroad by ensuring that U.S. origin animals and animal products meet health and welfare requirements of recipient countries. The program issued point of origin certificates for the export of approximately 909 thousand head of livestock, 30.2 million live poultry, 74.8 million eggs, 30 million day-old chicks, 9.3 million live fish, 103.2 million aquatic embryos and eggs, 10.3 million doses of semen, and 11,908 non-aquatic embryos.

Because international standards are science-based, several countries—including Argentina, Brazil, the Dominican Republic, Ecuador, Mexico, and Peru—placed restrictions on U.S. horses and birds in fiscal year 2002 due the presence of West Nile Virus in the United States. Other disease events, such as the diagnosis of Low Pathogenic Avian Influenza in several Eastern states in fiscal year 2002 and Exotic Newcastle Disease in California, Nevada, and Arizona in late 2002 and early 2003, also resulted in restrictions, significantly impacting live animal exports.

Through the Agricultural Quarantine Inspection program's EXCERT (export certification) system, APHIS facilitates the export of agriculture shipments. Over 4,000 certifying officials can access the information on certification requirements online. In fiscal year 2002, APHIS issued over 380,000 certificates for agriculture shipments. APHIS export certifications ensure that U.S. products meet the agricultural requirements of the country of destination. In fiscal year 2002, APHIS began the pilot phase of the Phytosanitary Certificate Issuance and Tracking database. This database captures export application information, documents inspection and certification information, and prints an original phytosanitary certificate on secure paper. The pilot phase involves 10 field locations, representing several State and County cooperators. APHIS will retain this certification responsibility while inspection operations are transferred to the Department of Homeland Security.

In fiscal year 2002, APHIS' Veterinary Biologics program issued 4,385 official certificates that indicate licensed production and testing facilities and products have met or exceeded marketing requirements. The regulated industry used these certificates to register their products for sale in foreign countries. The confidence that foreign regulators have in the U.S. veterinary biologics licensing, testing, and inspec-

tion system is reflected in their readiness to accept our products. Center for Veterinary Biologics (CVB) officials provided informational presentations at international conferences to bolster foreign regulators' confidence.

Resolve trade barrier issues related to animal and plant health. As modern trade agreements prohibit onerous tariffs and similar trade barriers, some countries may resort to "sanitary and phytosanitary" concerns—that is, claims that American agricultural exports carry pests and diseases not present in their countries. Those claims may not be science-based. APHIS fills the crucial role of gathering and analyzing the scientific evidence to refute such claims or recommend measures to reduce the impact of other country's SPS concerns.

Officials with the Trade Issue Resolution and Management program work to minimize trade disruptions caused by animal and plant health issues. Personnel overseas participate in negotiations, work with standard-setting organizations, and facilitate the capacity of countries to recognize and respond to agriculture health issues that restrict trade. They coordinate these activities with domestic staff who resolve issues that trading partners may have with U.S. products or handle negotiations on bilateral or multilateral issues. APHIS' efforts contributed to the opening or retention of $1.1 billion in export markets in fiscal year 2001, the latest data available. These accomplishments related to products as diverse as cherries, tobacco, and poultry.

The job of ensuring that animal and plant health issues are not used unfairly as barriers to trade gets more complicated as trade increases. Recent agreements and the efforts of the World Trade Organization have reduced the traditional barriers to trade in agricultural products. Countries wishing to protect their markets from competition may turn to sanitary and phyosanitary (SPS) barriers. To retain or open markets, APHIS technical experts must be ready to respond to challenges involving new animal and plant health issues.

Even though USDA, with APHIS assistance, persuades other countries to accept American exports in principle, the importing country may attempt to stop the entry on actual shipments. Attachés are uniquely positioned to respond to day-to-day problems with individual shipments that are detained in ports overseas. Sometimes the problems arise from a misunderstanding of a regulation, or the problem may be as simple as an incorrect notation on a phytosanitary certificate. Having these shipments detained could be costly for the exporter, whose product may spoil while the importing country is deciding on what to do with it. In fiscal year 2002, attachés' actions saved more than $53.2 million worth of products for agricultural exporters. For example, in May 2002, an APHIS attaché resolved an issue causing the detention of a $3 million shipment of rice to Costa Rica.

During fiscal year 2002, APHIS negotiated 44 new or revised export protocols for exporting poultry, livestock, and germplasm to numerous countries in the Americas, including Argentina, Bolivia, Brazil, Chile, the Dominican Republic, Ecuador, Guatemala, Mexico, Panama, and Peru. In addition, APHIS negotiated protocols with the Czech Republic for bovine semen and embryos, and with Lithuania, Hungary, and Estonia, for bovine embryos. Currently, APHIS is negotiating protocols with Peru and Nicaragua.

Increased trade in and concerns over genetically engineered products—particularly crops—have heightened international initiatives to harmonize and address assessments of products from both environmental and food safety perspectives. This has also led to discussion of mechanisms to address trade in these products, both bilaterally and multilaterally. A primary objective of APHIS' harmonization efforts is to maintain and enhance the use of science-based decision making, and to promote the credibility of U.S. regulatory bodies as independent, objective evaluators of product safety. APHIS has participated in the development of guidance and technical approaches in the Codex Alimentarius, the International Plant Protection Organization (IPPC), the North American Plant Protection Organization (NAPPO), the Cartagena Protocol on Biosafety, and the Organization for Economic Cooperation and Development (OECD). APHIS continued a joint project under the Transatlantic Economic Partnership (TEP) aimed at European Union and U.S. regulatory authorities accepting common data requirements as the basis for approval of biotechnology products. Success in the TEP process will facilitate a harmonized approval process for genetically modified organisms between North America and Europe.

Provide expertise and training in animal and plant health To facilitate agricultural trade, APHIS must provide technical services and information about animal and plant health to USDA's Foreign Agricultural Service and the U.S. Trade Representative, who have primary responsibility to negotiate trade agreements with other countries. We also need to help developing countries meet SPS Agreement requirements—which include having regulatory mechanisms in place to ensure the safe release and movement of agricultural products—and we need to help these

countries build better animal and plant surveillance capacity. Only through actively helping build health infrastructures can we be assured that other countries are sending healthy agricultural products to the United States. With the increasing volume of trade and movement of passengers, APHIS will likely have to rely more on the sanitary and phytosanitary export certificates of our trading partners. Trade is a two-way street; we cannot increase exports and simultaneously engage in protectionist practices. APHIS must protect U.S. agriculture from incursions of foreign pests and diseases without restricting trade. Trade agreements and the World Trade Organization oblige us to move quickly on foreign countries' requests to import into the United States. We also put together or participate in technical assistance projects with trading partners and potential trading partners. These technical assistance projects serve two roles. First, they assure trading partners that U.S. products are safe because they clearly explain U.S. sanitary and phytosanitary procedures. Secondly, they help other countries develop a regulatory infrastructure that will make it possible to safely take part in trade. Particularly aimed at developing countries, these projects aim to build new markets for U.S products while helping those countries build their own agricultural industries.

The technical assistance projects we administer vary worldwide in terms of the means of information dispersal. Examples include epidemiology training for visitors from overseas or distance learning modules on SPS principles. The modules, which are available in a variety of media, are administered via attachés worldwide. APHIS also participates in the Foreign Agricultural Service's Cochran Fellowship program, which funds training programs for senior- and mid-level agriculturists from middle income countries and emerging democracies. In recent years, the Cochran program has funded numerous training programs related to the SPS issues of food safety, animal health, and plant quarantine.

The Veterinary Biologics program continued efforts to reduce trade measures limiting the sale of veterinary biological products overseas. Program officials continued technical and harmonization discussions with representatives of the American, Asian, European and U.S. biologics industries and regulatory officials. APHIS held individual meetings with regulatory officials from Australia and New Zealand to facilitate exchange of information and encourage discussions of regulatory issues.

A part of APHIS' Veterinary Diagnostics program assists foreign governments in the diagnosis of animal diseases by maintaining national and international laboratory recognition with the highest quality reference assistance and by conducting developmental projects for rapidly advancing technologies.

In fiscal year 2002, the Agency's National Veterinary Services Laboratories (NVSL) continued efforts in the veterinary diagnostics program to safeguard the United States from adverse animal health events. APHIS, along with the Cooperative State Research, Education, and Extension Service, the American Association of Veterinary Laboratory Diagnosticians Executive Board, and State laboratory directors, developed a pilot program of the National Animal Health Laboratory Network. The network is a national strategy to meld the nation's Federal, State, and local resources in order to respond to any type of animal health emergency, including bioterrorist events, newly emerging diseases, and foreign animal disease agents that threaten the nation's food supply and public health. During fiscal year 2002, USDA provided a total of $15.25 million in Homeland Security funding to 12 State diagnostic laboratories to use for improving biosecurity of facilities, communicating results, buying equipment, standardizing methods, and quality assurance.

During fiscal year 2002, NVSL provided training to 798 State, Federal, private, and foreign participants for a total of approximately 303 training days. This included 13 formal APHIS training courses focusing on scrapie, tuberculosis, equine infectious anemia, blue tongue, bovine leukosis virus, brucellosis, leptospirosis, and lab biosafety. Six foreign animal disease training schools were also conducted at the Foreign Animal Disease Diagnostic Laboratory on Plum Island for a total of 197 participants. In addition to the formal courses, NVSL also provided bench training in EIA, brucellosis, Johne's, Salmonella, pseudorabies, scrapie, avian influenza (AI), West Nile virus, and contagious equine metritis.

FISCAL YEAR 2004 BUDGET REQUEST

American agriculture is a tremendous resource. To protect this resource, we must safeguard the health of our animals, plants, and ecosystems. The value of this resource is increased when you consider the economic benefits of trading our agricultural products overseas for other goods and services. Safeguarding our agricultural wealth and facilitating safe agricultural trade go hand in hand and require several activities. To carry out these activities, we request $694.9 million for the salaries and expenses account. We request a pay increase of $9.3 million and a decrease of

slightly more than $1 million because of information technology procurement efficiencies. Our requested program level changes are outlined below. In our building and facilities account, we request $5 million, a decrease of $5 million for a one-time project from fiscal year 2003 level, to carry out basic maintenance and repair activities.

The proposed funding for the Agricultural Quarantine Inspection (AQI) appropriated program reflects funding of future activities for the Automated Targeting System through mandatory, rather than discretionary funding. In addition, the $21.3 million request for AQI excludes the border inspection programs that have been transferred to the Department of Homeland Security (DHS). The fiscal year 2004 budget also recognizes the transfer of the Plum Island Animal Disease Center to DHS, which will receive some program funds and necessary funding to operate the facility. Both USDA and DHS will share program funds to reflect their needs, working closely to keep agricultural pests and diseases out of the United States.

Funding for ongoing programs to combat pests and disease is based on the recognition that the Federal Government, and affected States and localities, as well as producers and other private cooperators benefit from eradication. Therefore, we will be proposing a rule in the Federal Register to solicit public comment prior to finalizing before October 1, 2003 which establishes criteria to share program responsibilities in a reasonable manner. For that reason, the fiscal year 2004 budget allocates funding among the Federal Government and cooperators based on consistent program criteria which recognizes a significant Federal responsibility, and takes into account cooperator ability to pay as well as other risk based factors. Federal funding for these ongoing programs would still range from 57 percent to 70 percent, and could in other circumstances be as great as 100 percent.

The budget includes a total of $26.7 million for the boll weevil program, based on a 20 percent Federal cost share and a reduction of 35 percent in program acres based on long-term program goals.

To successfully safeguard the health of agricultural animals, plants, and ecosystems in the United States, we must begin overseas where those pests and diseases currently exist. To enhance our offshore threat assessment and risk reduction activities, APHIS requests a total of $1 million for classical swine fever eradication in the Dominican Republic and Haiti and $2.9 million to eradicate tropical bont tick from Antigua and prevent its spread to other islands.

To reduce the risk of introduction of exotic invasive species, we must enhance our regulatory enforcement and monitoring activities. We request $881,000 for an aerial sterile Medfly preventive release program in California and Florida. A total of $9.6 million is proposed for the animal and plant health regulatory enforcement program including funds to continue Homeland Security Supplemental funded investigations of alleged violations, search garbage feeding operations, and document enforcement actions. An import/export program increase of $2.8 million will allow us to complete and maintain an animal tracking system and place database managers to identify pathways of exotic animal disease. We request $2.9 million to make a number of improvements associated with biosecurity. These include connecting field activities electronically to our Emergency Management Operations Center, enhancing identification protocols and analytical capabilities, developing a network of Foreign Animal disease diagnosticians, and conducting biosecurity awareness campaigns. We are proposing a total of $6.3 million to continue increased security at mission critical facilities.

To address the threat of biological terrorism directed at the nation's animal food supply, the Agency proposes an increase of $1.4 million in the veterinary biologics program and an increase of $3.3 million in the veterinary diagnostics program for enhanced laboratory network activities, anthrax diagnostics, and security clearances.

To prepare for the unlikely event of foot-and-mouth (FMD) entering the United States, we request $560,000 to increase the North American FMD vaccine bank doses by 1.25 million to 20.75 million.

The continued existence of pests and diseases in the United States hurts the American producer in several ways. First, their existence reduces yields and increases costs. Second, other countries will cite them as reasons to prohibit or place restrictions on our exports. APHIS has requests to address some of the most devastating pests and diseases. We propose $15 million in our chronic wasting disease program to increase grants to States and to assist in surveillance, disease management, diagnostic testing, communications, and information management. We need an additional $329,000 in the golden nematode program for increased surveillance, equipment, and cooperative agreement funding. We request $2 million to assist States in a long-range low pathogenic avian influenza control and prevention program. To ensure we can account for all hazardous materials used in our wildlife

services operations program, we request $1 million to create a hazardous materials database. We request a total of $3.5 million in the plum pox virus program to continue recent program success in eliminating and not finding any more disease.

The APHIS request does not contain an increase in the trade issues resolution and management program to enhance our ability to resolve trade barrier issues related to animal and plant health or in the biotechnology regulatory services program to improve existing products and spawn new technologies. The Office of the Secretary requests $6.6 million to be allocated among USDA Agencies for negotiating and monitoring trade agreements and for technical trade support in the areas of biotechnology regulatory services and sanitary and phyto-sanitary issues.

We also propose a reduction of $7.7 million associated with animal welfare user fees. This will allow the industry to cover an estimated 50 percent of the cost of enforcing the animal welfare regulations.

CONCLUSION

Simply stated, APHIS' mission is to protect the health and value of America's agricultural and natural resources. This mission carries two goals—to safeguard the health of animals, plants, and ecosystems in the United States and to facilitate safe agricultural trade. Our safeguarding goal requires us to: (1) conduct offshore threat assessment and risk reduction, (2) regulate and monitor to reduce the risk of introduction of exotic invasive species, (3) ensure safe research, release, and movement of agricultural biotechnology events, veterinary biologics, and other organisms, (4) manage issues related to the health of U.S. animal and plant resources and conflicts with wildlife, and (5) respond to emergencies and emerging issues—surveillance, quick detection, containment, and eradication. Our facilitating trade goal requires that we: (1) document the health status of U.S. agriculture and related ecosystems, (2) certify the health of animals and plants and related products for export and interstate commerce, (3) resolve trade barrier issues related to animal and plant health, and (4) provide expertise and training in animal and plant health. There is a continuum between the goals and a connected, inseparable relationship among the objectives. We cannot improve, or strengthen one goal without improving or strengthening the other.

I am proud of the APHIS mission, its goals, and its objectives. I also am proud of all of the men and women of APHIS who have dedicated their careers to improving the health and profitability of America's animal and plant resources. Their dedicated efforts, coupled with the Committee's unwavering support, have truly helped American agricultural producers overcome pests, diseases, and economic uncertainty. I will close by saying that Progressive Farmer, one of America's oldest and most widely circulated agricultural publications selected "The People of APHIS" as winners of the 2003 People of the Year recognition. Since 1937, this is the first time the award has gone to a group of people. This indeed is quite an honor and recognizes the character and dedication of everyone at APHIS.

On behalf of APHIS, I appreciate all of your past support and look forward to even closer working relationships in the future. We are prepared to answer any questions you may have.

PREPARED STATEMENT OF A.J. YATES, ADMINISTRATOR, AGRICULTURAL MARKETING SERVICE

Mr. Chairman and Members of the Committee, I am pleased to have this opportunity to represent the Agricultural Marketing Service—AMS—in presenting our fiscal year 2004 budget proposal.

MISSION

AMS activities support agricultural marketing. Formally stated, the Agency's mission is to facilitate the marketing of agricultural products in the domestic and international marketplace, ensure fair trading practices, and promote a competitive and efficient marketplace to the benefit of producers, traders, and consumers of U.S. food and fiber products. We accomplish this mission through a variety of voluntary fee-based services and publicly funded activities that help our customers find ways to better market food and fiber products and improve their profitability. AMS helps to make the Nation's agricultural markets work efficiently by making sure that all producers and traders have equal access to market information; by assuring them that quality and other product representations are accurately described; by providing pesticide residue and microbiological data that support science-based risk assessment; by providing "how to" technical expertise to growers, shippers, and mar-

ket facilities; by helping to develop improved or alternative market outlets; and by helping producers adjust to consumer trends.

To be successful, we continually monitor the needs of our customers in the agricultural industry, develop strong partnerships with cooperating State agencies, and adopt new technology to improve our effectiveness. Since most of our user-funded services are voluntary, we always remain conscious of cost while being responsive to customer needs.

AMS depends on strong cooperative partnerships with States and other Federal agencies. Our Market News, Shell Egg Surveillance, Pesticide Data, Microbiological Data, Pesticide Recordkeeping, and Federal Seed programs all depend on their State partners to help collect and disseminate information, provide inspections, and otherwise maximize the value of State and Federal programs by sharing and coordinating the use of available resources.

One of the ways we continue to improve our service is through public electronic access to information and services. AMS offers online application for services, filing for protection under the Perishable Agricultural Commodities Act, public comment on rulemaking, and bidding on Federal commodity purchases. Market news users can now access all current market news reports through the AMS Internet home page (www.ams.usda.gov), use search engines to retrieve recent historical data from an 18-month archive, and link to other Internet sites that carry related information.

For fiscal year 2004, AMS will maintain a high level of program delivery while continuing to implement program enhancements without an increase in funding. Therefore, I would like to describe some of AMS' significant accomplishments during fiscal year 2002 and our activities in 2003.

GLOBAL AGRICULTURAL MARKETING

AMS offers a range of services that give sellers of agricultural products a competitive advantage in the global marketplace. For example, our Transportation Services and Pesticide Data Programs provide information to facilitate agricultural commodity exports. Our AMS grading and laboratory testing programs offer product, production process, and equipment certifications to support compliance with export specifications.

We initiated our Global Market Expansion program in fiscal year 2002 to strengthen our support of export marketing for agricultural products. Under this activity, AMS participates in international standards organizations such as United Nations Codex Alimentarius Commission committees, International Dairy Federation Standing Committees, U.N. Economic Commission for Europe, Organization for Economic Cooperation and Development Seed Scheme, International Standards Organization, International Seed Testing Association, North American Free Trade Agreement Working Groups, World Meat Congress, International Calibration Cotton Standards Committee, International Textile Manufacturers Federation, U.S. National Committee for the International Institute of Refrigeration Working Committees, and several bilateral Consultative Committees on Agriculture. AMS experts served on, and in several cases headed, U.S. delegations to meetings of these international food and fiber standards-setting organizations.

AMS also provides technical expertise in negotiations on international standards. In 2002, we worked with U.S. trade officials to delay China's adoption of cotton standards that lack recognized measurement technologies and could have posed a barrier to U.S. cotton exports. AMS led the development of lamb and poultry quality standards that will serve as models for government and industry throughout Europe. We actively participated in developing a model export certificate for milk and milk products, international dairy standards and a code of hygienic practices for milk and milk products. We provided expertise on finalizing the technical requirements for testing meat products for hormones and veterinary drugs destined for export to the European Union and helped develop the U.S./Chile free trade agreement that will make U.S. beef eligible for export to Chile.

Through such participation, AMS is able to influence the design of food quality standards and model inspection protocols so that they are fair to U.S. shippers and they do not become barriers to U.S. agricultural trade. The Agency will continue to do its part in helping to reduce trade barriers relating to commodity standards and product testing by serving as delegates and by leading international committees and organizations.

For fiscal year 2003, AMS is expanding Market News reporting on international markets so that U.S. growers and traders have the information they need to make informed production and sales decisions. Market news reports provide access to a centralized, consistent, public source of timely information on international prices and trade volume. The foundation for enhanced reporting from Western Hemisphere

countries has already been laid through AMS' initiation of the Market Information Organization of the Americas (MIOA). The MIOA brings together market reporting services from 18 countries in North, South, and Central America to harmonize product definitions, reporting formats, and information exchange.

PESTICIDE DATA

AMS supports domestic and export marketing of U.S. food products through its Pesticide Data Program (PDP). PDP is a unique and valuable source of statistically valid data on pesticide residues in food and water. The program provides information to the Environmental Protection Agency that is vital for realistic assessments of dietary risk from pesticides on food commodities available in the marketplace. The data collected benefits growers by enabling regulators to make better-informed decisions on pesticides. Furthermore, PDP is instrumental in providing data that addresses domestic and international public concerns about the effects of agricultural pesticides on human health and environmental quality. Exporters use PDP data to verify for foreign governments and buyers that U.S. agricultural commodities are safe for consumption.

Over the past 11 years, the program has tested 57 commodities, including fruit and vegetables, grains, milk, peanut butter, poultry, beef, juices, and drinking water. The results from PDP testing provide comparative pesticide residue data between fresh versus processed commodities, and an in-depth comparison for selected domestic versus imported commodities. Of the more than 12,000 samples tested in calendar year 2001, 82 percent were domestically produced and 18 percent were imported. PDP procedures are designed to detect, verify, and report low-level pesticide concentrations. Pesticide residues only exceeded established tolerance levels in three-tenths of 1 percent of the samples, although residues were detected on 56 percent of all samples. In fiscal year 2002, the program performed over 100,000 analyses on 13,000 samples.

In March 2001, the program began testing finished drinking water samples. During fiscal year 2002, the drinking water survey was expanded to include sampling in Colorado, Kansas and Texas, while continuing sampling of municipal water systems in California and New York.

Importantly, PDP is built on Federal-State partnerships with 10 States—California, Colorado, Florida, Maryland, Michigan, New York, Ohio, Texas, Washington and Wisconsin. These States collect and test commodities for pesticide residues. In 2003, AMS received additional funding for PDP. Most of the increase will be used to offset rising operational costs at the State level. These funds will support infrastructure improvements and allow the Pesticide Data Program to add data on new commodities and residues. We also plan to complete the effort to achieve International Standards Organization accreditation for our PDP laboratories.

MICROBIOLOGICAL DATA

Our experience in establishing a successful data collection program was of enormous assistance in initiating our Microbiological Data Program. MDP is designed to gather baseline data to assess the risks of microbial contamination of fruits and vegetables, if any. The program collects information regarding the incidence, number and species of foodborne pathogens and indicator organisms on domestic and imported fresh fruits and vegetables.

In fiscal year 2002, AMS worked with cooperating States and interested industry parties to initiate microbiological data collection and testing. AMS developed operating procedures with FDA, the Centers for Disease Control and Prevention (CDC), and State laboratories. Samples of five commodities were collected in the ten cooperating States and were tested in State and Federal laboratories. During 10 months of sample testing, approximately 19,000 analyses were performed on 9,400 samples. The first report will be published during 2003 with calendar year 2002 data. The data will be provided to public health agencies and the food industry for decision-making and evaluation of procedures intended to reduce or eliminate harmful microorganisms from foods.

NATIONAL ORGANIC CERTIFICATION PROGRAM

The purpose of AMS' National Organic Certification program is to facilitate trading of organic products by verifying for buyers and consumers across the United States and internationally that U.S. organic food labeling is accurate and consistent. The program established national standards for organic production and handling, and is accrediting certification agents who can now conduct annual on-site inspections to verify that organic products meet these standards. The program has received 134 applications for accreditation. Fifty-three of the applicants were private

domestic certification agents; 20 were State certification agents; and 61 were foreign. Through March 14, 2003, AMS has accredited 84 applicants, 37 of whom have been site-evaluated for compliance with the program. AMS has also implemented a program to approve State organic programs for production and handling operations within that State. State organic programs will administer a compliance program for enforcement of the National Organic Program and any more restrictive requirements approved by the Secretary. Six States have applied and are under review or are providing more information.

AMS entered into cooperative agreements with 14 States to distribute to organic producers the cost share funds authorized under the Federal Crop Insurance Act. The National Organic Certification Cost-Share Program, authorized by the Farm Security and Rural Investment Act of 2002, made funds available to assist certified organic producers and handlers in all States. To date, we have agreements with 44 States to distribute these cost share funds.

As of October 21, 2002, use of the official USDA organic seal is permitted for certified organic fresh and processed products. Also, during 2002, AMS developed procedures for enforcement, appeals, international recognitions, and authorization to issue export certificates. Consequently, the organic seal can be used as a marketing tool for exported products. AMS has recognized the conformity assessment programs of four foreign governments, worked with the Foreign Agricultural Service to negotiate recognition of the U.S. organic program by the Japanese Ministry of Agriculture and begun equivalency negotiations with the European Union.

MANDATORY PRICE REPORTING SYSTEM

AMS' Livestock Mandatory Price Reporting (LMPR) program addresses concerns about market concentration in the livestock industry and resulting price discovery problems in the marketplace. On April 2, 2001, AMS implemented the LMPR system to meet the requirements of the Livestock Mandatory Reporting Act.

Mandatory reporting provides marketing information on 80 to 95 percent of the volume of all cattle, boxed beef, slaughter hogs, sheep, lamb meat and imported lamb meat traded. Large volume packers and importers report the details of their transactions to AMS. Mandatory reports include information on pricing, contracting for purchase, and other market transaction data for livestock and livestock products. Specifically, mandatory market news covers the prior day swine market; forward contract and formula marketing arrangement cattle purchases; packer-owned cattle and sheep information; and sales of imported boxed lamb cuts.

LMPR is an ambitious effort to provide livestock market information on a near real-time basis over the Internet. Packers submit data by lot, several times a day to AMS via a secure Internet connection. AMS' automated system processes thousands of pieces of market information from the livestock industry and generates market news reports within one hour after receipt of the data. During 2002, AMS was able to release data through the electronic system within an hour of receipt 95 percent of the time.

The system is designed to protect the confidentiality of packers. No data has been released that compromised the identity of source packers. The confidentiality provisions were modified in August 2002, which resulted in the release of 95 percent, or 86 of the originally anticipated 91 mandatory reports. The remaining reports represent thinly traded items and we continue to search for ways to report the data while maintaining confidentiality. In addition to the original set of reports, AMS has developed and begun releasing 16 new reports that improve the marketing information available on the cattle and boxed beef markets. In November 2002, the program began releasing cattle reports utilizing new formats to provide the industry with more regional information and volume accumulation data. AMS developed the new formats based on incoming data and feedback from the industry concerning the data most important in assessing market conditions. AMS continues to work to improve security and expand or improve on existing reports. Authorization for mandatory reporting expires at the end of fiscal year 2004.

COUNTRY OF ORIGIN LABELING

The 2002 Farm Bill (Farm Security and Rural Investment Act of 2002) required USDA to issue voluntary country of origin labeling guidelines for use by retailers who wish to notify their customers of the country of origin of beef, lamb, pork, fish, perishable agricultural commodities, and peanuts. The voluntary country of origin labeling guidelines were published in October 2002 and comments on their utility were received until April 2003. Over 1000 comments were received.

The country of origin labeling provisions of the 2002 Farm Bill also require USDA to publish regulations implementing a mandatory country of origin labeling program

by September 30, 2004. AMS has begun the process of developing the mandatory regulations. To assist in this process, USDA has scheduled a series of 12 listening and education sessions across the United States to receive input from interested parties. USDA plans to publish the regulations implementing the mandatory program as a proposed rule and will provide a 90-day comment period for interested parties.

WHOLESALE, FARMERS AND ALTERNATIVE MARKETS

AMS supports direct marketing to help growers sell their farm products directly to consumers, enhancing the farmers' ability to thrive in their businesses. Direct marketing includes farmers markets, pick-your-own farms, roadside stands, subscription farming, community-supported agriculture, and catalog sales. Direct marketing has been gaining in popularity and especially benefits small and medium-sized farm operators. Farmers markets, for example, are an integral part of the urban/farm marketing chain. In 2002, the National Farmers Market Directory listed over 3,100 farmers markets in the U.S. AMS has been working with FNS to coordinate AMS' farmers market development activities with FNS' nutrition programs. A report on this effort is nearing completion and will be forwarded to Congress upon final approval.

SECURITY INITIATIVES

In cooperation with Departmental planners, AMS has developed a comprehensive strategy to address homeland security issues. AMS has a fully-developed and tested Continuity of Operations Plan and two fully equipped emergency relocation sites. We have identified our mission critical facilities and have strengthened the security of those facilities by installing emergency power generators, access control systems, intrusion detectors, and additional exterior lighting. The Agency has expanded its written instructions and is developing a training program for inspectors, auditors, and graders on monitoring for and reporting contamination or tampering of food products. AMS is currently establishing a small office of safety and security to focus on these issues and to coordinate improvements in security measures.

ELECTRONIC GOVERNMENT

AMS has taken a leadership role in the transition to electronic government. We are working closely with USDA partners to establish electronic access to core services. AMS led the business case for the Department's web portal project and is conducting an Agency portal pilot for market news information. We have also worked to create real-time interaction with our customers. A system known as e-Work allows customers to electronically submit information forms to AMS. The system then processes the forms and generates messages to the customer advising them of the status of their request. In other initiatives, AMS was one of the first agencies in USDA to use electronic authentication in its Livestock Mandatory Price Reporting system. Our Food Quality Assurance program is creating a website for use by institutional food service professionals to learn about sources of new products or find locations approved to further process USDA-purchased commodities. In addition, AMS is working with FNS and FSA to modernize the current commodity purchase management system to a web-based supply chain management system. We will continue to look for ways to provide our customers with better access to our services.

BUDGET REQUEST SUMMARY

AMS has proposed no funding increases for program activities for fiscal year 2004. Instead, we will continue our efforts to improve our efficiency and customer service with the funding currently available. Our total budget request includes $75 million for Marketing Services, which includes an increase for pay costs, partially offset by a decrease for savings associated with information technology centralization and improvement. We also include a decrease of $1 million for the Pesticide Data Program. This funding was provided in fiscal year 2003 for increased testing of drinking water.

We are requesting the current funding level of $1.3 million for Federal-State Marketing Improvement Program grants under Payments to States and Possessions. Our request for $26.4 million in Section 32 Administrative funds includes an increase for pay costs.

AMS will continue its mission to assist the agricultural industry by facilitating domestic and international marketing. Thank you for this opportunity to present our budget proposal.

PREPARED STATEMENT OF DONNA REIFSCHNEIDER, ADMINISTRATOR, GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION

Mr. Chairman and Members of the Committee, I am pleased to highlight the accomplishments of the Grain Inspection, Packers and Stockyards Administration (GIPSA), and to discuss the fiscal year 2004 budget proposal.

GIPSA is part of USDA's Marketing and Regulatory Programs, which works to ensure a productive and competitive global marketplace for U.S. agricultural products. GIPSA's mission is to facilitate the marketing of livestock, poultry, meat, cereals, oilseeds, and related agricultural products, and to promote fair and competitive trading practices for the overall benefit of consumers and American agriculture.

GIPSA serves in a regulatory capacity, with an emphasis on service to the regulated industries. The Packers and Stockyards Programs promote a fair, open, and competitive marketing environment for the livestock, meat, and poultry industries. The Federal Grain Inspection Service provides the U.S. grain market with Federal quality standards, a uniform system for applying these standards, and impartial, accurate grain quality measurements that promote an equitable and efficient grain marketing system. Overall, GIPSA helps promote and ensure fair and competitive marketing systems for all involved in the merchandising of livestock, meat, poultry, and grain and related products.

ORGANIZATION

GIPSA supervises 14 State and 43 designated private agencies for grain inspection and weighing services at domestic locations; provides supervision and other services from 20 field offices; and handles appeals of grain inspection services in Kansas City, Missouri. GIPSA also maintains 3 Packers and Stockyards Programs regional offices that specialize in poultry, hogs, and cattle/sheep.

For fiscal year 2004, the budget proposes a program level for salaries and expenses of about $42 million. Of this amount, $18 million is devoted to grain inspection activities for standardization, compliance, and methods development, and $24 million is for Packers and Stockyards Programs.

The 2004 budget includes two program increases. I will mention these now, but expand on these increases when I discuss the budget in more detail.

About $1 million of the increase is to implement a new pilot program to audit the steer and heifer meatpackers. The Packers and Stockyards Programs have never audited a large packer. We anticipate that an audit of large meatpackers will result in substantially better protection to the regulated industries. $0.5 million of the increase is to conduct a comprehensive, industry-wide review of the Packers and Stockyards Act and regulations. Given dramatic structural changes in the industries covered under the P&S Act, the Packers and Stockyards Programs are preparing to undertake a complete review of the Packers and Stockyards Act and its regulations, something that has not been done to date.

In addition to these increases, the Administration proposes an increase in the budget of the Office of the Secretary to support crosscutting trade and biotechnology activities of the Department, including regulatory, market access and trade barrier removal activities. Increased GIPSA efforts related to biotechnology may be funded from the proposed Office of the Secretary funds.

The Administration also proposes that GIPSA implement two new user fee proposals. New user fees would be charged to recover the costs of developing, reviewing, and maintaining official U.S. grain standards used the by the grain industry. Those who receive, ship, store, or process grain would be charged fees estimated to total about $5 million to cover these costs. Also, the Administration proposes that the Packers and Stockyards Programs be funded by new license fees of about $24 million that would be required of packers, live poultry dealers, poultry processors, stockyard owners, market agencies, and dealers, as defined under the Packers and Stockyards Act.

I would like to discuss the activities of the Packers and Stockyards Programs and Federal Grain Inspection Service relative to the fiscal year 2004 budget.

PACKERS AND STOCKYARDS PROGRAMS

GIPSA's Packers and Stockyards Programs (P&SP) administers the Packers and Stockyards Act (P&S Act) to promote fair and open competition, fair trade practices, and financial protection in the livestock, meat packing, meat marketing, and poultry industries. The objective of the P&S Act is to protect producers, growers, market competitors, and consumers against unfair, unjustly discriminatory, or deceptive practices that might be carried out by those subject to the P&S Act. To meet this objective, GIPSA seeks to deter individuals and firms subject to the P&S Act from

engaging in anti-competitive behavior, engaging in unfair, deceptive, or unjustly discriminatory trade practices, and failing to pay livestock producers and poultry growers. GIPSA initiates appropriate corrective action when there is evidence that firms or individuals have engaged in anti-competitive, trade, payment or financial practices that violate the P&S Act.

The livestock, meatpacking, and poultry industries are important to American agriculture and the Nation's economy. With only 169 employees, GIPSA regulates these industries, estimated by the Department of Commerce in fiscal year 2002 to have an annual wholesale value of $118 billion. At the close of fiscal year 2002, 6,024 market agencies and dealers, and 2,064 packer buyers were registered with GIPSA. In addition, there were 1,510 facilities that provided stockyard services, with an estimated 6,000 slaughtering and processing packers, meat distributors, brokers and dealers, and 205 poultry firms operating subject to the P&S Act.

Our regulatory responsibilities are the heart of our mission to administer the P&S Act. To this end, GIPSA closely monitors practices that may violate the P&S Act. Our top priority continues to be investigating complaints alleging anti-competitive, unjustly discriminatory, or unfair practices in the livestock, meat, and poultry industries. Last year, GIPSA conducted over 1,400 investigations. As a result of these investigations, the Packers and Stockyards Programs helped restore over $37 million to the livestock, meatpacking, and poultry industries. This is the largest amount GIPSA has ever reported to Congress and constitutes more than double the amount that P&SP received in appropriated funding.

GIPSA divides its regulatory responsibilities into three areas: financial protection, trade practices, and competition. In the area of financial protection, GIPSA continued to provide payment protection to livestock producers and poultry growers in a year where the livestock, meatpacking, and poultry industries faced tremendous financial pressures. Financial investigations last year resulted in $4.3 million being restored to custodial accounts that are established and maintained for the benefit of livestock sellers. Livestock sellers recovered over $3.2 million under the P&S Act's packer trust provisions. During fiscal year 2002, 81 insolvent dealers, market agencies and packers corrected or reduced their insolvencies by $26.6 million. In addition, GIPSA's financial investigator's analyzed eight complex packer trusts and one poultry trust in which filed claims exceeded $15 million; GIPSA also analyzed more than 800 bond claims exceeding $30 million. I would note that GIPSA provides its analysis as a courtesy to the industry; it has no statutory authority to compel payment by the trustee or bond surety.

In its Trade Practices Programs, GIPSA continued to promote fair trading between industry participants and, in fiscal year 2002, targeted its resources at working with industry members to secure appropriate bonding levels. While the overall numbers of individuals required to be bonded under the P&S Act dropped, the total value of bonds available to unpaid sellers increased by $13 million. Much of GIPSA's work in the Trade Practices Program focuses on insuring accurate weights and prices. GIPSA continued to work with local States weights and measures programs to provide scale training and to secure State assistance in testing every scale used to weight livestock or live poultry twice a year. In addition, GIPSA initiated or completed 63 investigations of weight and price manipulation of livestock. Some of these investigations are on-going. GIPSA also investigated the operations of 53 live poultry dealers; most of these investigations examined whether live poultry dealers were in compliance with contracts entered into with poultry growers. We are continuing to work with members of the regulated industries to develop industry standards on new technologies that are entering the marketplace to evaluate and price livestock purchased on a carcass merit basis.

GIPSA continues to develop its Competition Program, and GIPSA's Competition Program is starting to yield results. Last year, GIPSA hired a new Competition Branch Chief who works very closely with the Deputy Administrator, the Office of the General Counsel, and the competition units in the field office to fully implement the recommendations contained in the September 2000 General Accounting Office report. During fiscal year 2002, the Competition Branch evaluated complaints regarding attempted restriction of competition, failure to compete, buyers acting in concert to purchase livestock, apportionment of territory, unlawful price discrimination, and predatory pricing. Of these complaints, two resulted in a letter of notice that brought the firm into compliance with the P&S Act; the remaining complaints were not supported by evidence. In addition to these investigations, the Competition Program, with the Commodities Futures Trading Commission (CFTC), investigated the sharp decline of livestock prices that followed the events of September 11, 2001 to determine if packers were taking advantage of the situation in violation of the P&S Act. GIPSA and the CFTC also conducted a joint review of the cash and futures markets based on rumors of foot and mouth disease in Kansas. GIPSA con-

tinues to work closely with the CFTC, attending CFTC Commissioner briefings on the cattle, hog, and meat markets.

Competition investigations are complex, and the results are not immediately visible. P&SP often attempts to resolve competitive issues informally, rather than go through the litigation process because of the resources, cost, and time involved. For example, the USDA's Judicial Officer just issued a decision in which he found that a major packer violated the P&S Act as we alleged in a complaint filed in 1999. While this may seem like a long time to resolve a complaint, it is comparable to private litigation. The competition program currently has several major investigations on-going. In addition to these investigations, the Competition Program is working more closely with the regulated industries, especially packers, to address the competitive implications of new practices prior to their implementation.

GIPSA's Rapid Response Teams remain a powerful tool to address urgent industry issues that place the industries in imminent financial harm. For example, after one of the major meatpackers declared bankruptcy on a Friday afternoon, we had rapid response teams in place at each of its plants and in its corporate offices on Monday morning to ascertain the financial condition of its slaughter operations. Last year, GIPSA rapid response teams investigated 40 situations across the Nation. During fiscal year 2002, these rapid response investigations contributed to returning $4.2 million to livestock producers and poultry growers.

GIPSA continues to work with violating firms to achieve voluntary compliance, and GIPSA continues to initiate appropriate corrective action when we discover evidence that the P&S Act has been willfully violated. During fiscal year 2002, GIPSA, with assistance from the Office of the General Counsel, filed 23 administrative or justice complaints alleging violations of the P&S Act. This represents more than a 50 percent increase over the number of complaints filed in fiscal year 2001.

GIPSA also has cooperative agreements with qualified researchers and research institutions that contribute valuable information to GIPSA's economic understanding of the livestock, meatpacking, and poultry industries. Two reports were completed in fiscal year 2002. Four cooperative agreements remain on-going.

GIPSA completed three additional reports that were submitted to Congress: "Assessment Report of the Cattle and Hog Industries, Calendar Year 2001," "Captive Supply of Cattle and GIPSA's Reporting of Captive Supply," and "Packers and Stockyards Programs Statistical Report 2000." Each of these reports is available on the GIPSA website.

To ensure that producers and growers are aware of the protections the P&S Act provides, the Agency provides a hotline (1–800–998–3447) by which stakeholders and others may anonymously voice their concerns. Last year GIPSA responded to and investigated issues raised by 118 callers. These calls were in addition to calls received in our regional offices. GIPSA also increased its outreach activities. GIPSA conducted 32 orientation sessions for new auction market owners and managers and 12 feed mill orientations to educate them about their fiduciary and other responsibilities under the P&S Act. GIPSA's Deputy Administrator met with top officials from the largest six steer and heifer packers to discuss issues of concern to the Agency and to the packers. These visits protect livestock producers and poultry growers who rely on P&SP to promote a fair, competitive, and financially sound marketplace. GIPSA personnel regularly participate in meetings with industry associations at the local, State, and national levels. During these meetings, GIPSA officials share our concerns, and listen to the concerns expressed by industry participants to ensure that we continue to remain abreast of problems and concerns in the livestock, meat, and poultry industries, and to better understand the marketing options and constraints these industries face. On the front lines, GIPSA's resident agents, situated at 28 locations across the Nation, maintain open communications with State officials to discuss areas of overlapping jurisdiction.

GIPSA is now in the process of updating memoranda of understanding with all 50 States to ensure that we maintain solid working relationships with our State partners. GIPSA recognizes that it is essential to stay in touch with growers, producers, and Federal and State representatives to understand, stay abreast of, and anticipate issues confronting the industries it regulates. To this end, GIPSA officials participated in several committees, including a commission established by the Governor of Missouri to address marketing issues on livestock and a task force established by the National Pork Producers Council to address hog marketing issues. GIPSA's outreach efforts have fostered a broader base of understanding with those we regulate and those intended to benefit from the protections of the P&S Act. We will continue and expand this effort.

FEDERAL GRAIN INSPECTION SERVICE

The Federal Grain Inspection Service (FGIS), provides the U.S. grain market with Federal quality standards and a uniform system for applying these standards. FGIS has both service and regulatory roles, and was founded to provide impartial, accurate quality and quantity measurements to create an environment that promotes fairness and efficiency. GIPSA administers uniform, national grain inspection and weighing programs established by the U.S. Grain Standards Act, as amended.

Under provisions of the Grain Standards Act, most grain exported from the United States must be officially weighed. A similar requirement exists for inspection, except for grain which is not sold or described by grade. Inter-company barge grain received at export port locations also must be officially weighed. And, the Act requires that all corn exported from the United States be tested for aflatoxin prior to shipment, unless the contract stipulates that testing is not required.

Mandatory inspection and weighing services are provided by GIPSA on a fee basis at 38 export elevators, including 5 floating elevators. Under a cooperative agreement with GIPSA, the Canadian Grain Commission provides official services, with GIPSA oversight, at seven locations in Canada exporting U.S. grain. Eight delegated States provide official services at an additional 19 export elevators under GIPSA oversight.

Grain exporters shipping less than 15,000 metric tons of grain abroad annually are exempt from mandatory official inspection and weighing requirements. Grain exported by train or truck to Canada or Mexico also is exempt from official inspection and weighing requirements.

Official inspection and weighing of U.S. grain in domestic commerce are performed upon request and require payment of a fee by the applicant for services. Domestic inspection and weighing services are provided by 58 designated agencies that employ personnel licensed by GIPSA to provide such services in accordance with regulations and instructions.

Under the Agricultural Marketing Act of 1946, GIPSA administers and enforces certain inspection and standardization activities related to rice, pulses, lentils, and processed grain products such as flour and corn meal, as well as other agricultural commodities. Services under the Agricultural Marketing Act are performed upon request on a fee basis for both domestic and export shipments by either GIPSA employees or individual contractors, or through cooperative agreements with States.

GIPSA knows that customers also want more information about the products they are purchasing and consuming. Some of the attributes that they want are impossible, impractical, or expensive to be determined by traditional testing. That is why GIPSA is developing a process verification program that should help us mirror some of the identity preservation and marketing systems currently used in the private sector.

Field dried corn would be one example of a quality attribute that can't be determined by testing. Process verification is one way that GIPSA could meet the demand for this kind of information. That does not eliminate the need for our traditional testing, but adds important information to the marketing of the product.

In a recent customer survey, 20 percent of industry folks consider the need to handle identity preserved grain important today. But more than two-thirds of the same folks think this will be important in five years. The message here is clear. The changing market demands a way to document and validate product differentiation in the very near future.

We have received inquiries from a wide range of agri-businesses. We have been contacted by individual producers, national and State producer associations, feed manufacturers, coop and multi-national grain companies and others. The underlying theme is that they're seeking to preserve their differences in the marketplace by getting third-party verification of their quality management systems.

Today, protecting the identity of a specialty corn or other process has some value. In the future, this ability will be very important to a growing part of the marketplace.

The change in customer wants and needs leads us to continually examine how we support and facilitate the grain markets. As the grain markets evolve in response global trade, increased consumer demands, and technological advances, GIPSA is working with market participants to ensure that the inspection system and grain standards best reflect the overall market needs.

To achieve this, we will introduce new internet-based services to improve the internal efficiencies of our operations and to deliver our customers with high speed, quality grain inspection results. At the touch of a button, buyer and seller will have the necessary quality information to process sales transactions effectively and efficiently. Our aim is to be able to provide internet-based service that connects us, the

official system, and our customers in an electronic business environment where we can interact with greater speed and efficiency.

We are also working with market participants to determine how best the grain standards can reflect the market value of future products. Breeders are working with end users to tailor corn for specific end uses. These advances have already created value-added markets, such as nutritionally dense corn and high extractable starch corn. Further developments could lead to the subdivision of traditional commodity corn into multiple end-use types, such as poultry, swine or cattle feed corn. The standards will help the market assess the value of the commodity in light of specific end uses.

And most of all, our aim is to be flexible, so that we can serve a larger portion of the grain markets. Reacting to market conditions that we face today is insufficient. Anticipating what the market will need tomorrow is necessary. Our efforts are focused on the future as we work to anticipate marketing needs in a rapidly changing environment.

Further, from the almost 3,000 comments received on our advance notice of proposed rulemaking that sought public comment on how USDA can best facilitate the marketing of grains, oilseeds, fruits, vegetables, and nuts in today's evolving marketplace, GIPSA is considering proposing a Process Verification Program to apply internationally-recognized quality management standards to verify the quality process, whether related to biotechnology or not, used to supply a product rather than testing the actual grain itself (e.g., non-genetically-modified corn). This would allow producers, marketers, suppliers, and processors to assure customers of their processes to provide consistent quality products.

2004 BUDGET REQUEST

To fund these initiatives, GIPSA's budget request for fiscal year 2004 is $41.7 million under current law for salaries and expenses and $42.5 million for our Inspection and Weighing Services. There is an increase of $612,000 for pay costs contained in the budget. GIPSA will also be submitting legislation to collect $28.8 million in new user fees in fiscal year 2004, $5.2 million for the grain standardization activities and $23.5 million for the Packers and Stockyards Programs.

The President's fiscal year 2004 budget proposes a current law request for grain inspection of $18.1 million. The only changes from fiscal year 2003 budget levels are an increase of $282,000 for pay costs and a decrease of $56,000 for Information Technology savings.

The President's fiscal year 2004 budget proposes a current law request for Packers and Stockyards Programs of $23.5 million. As I mentioned before, there are proposed increases of $994,000 to implement a pilot program to audit the steer and heifer meatpackers to be offset by proposed user fees, and $500,000 to enhance compliance and review the Packers and Stockyards Act. Additional changes from fiscal year 2003 budget levels are an increase of $330,000 for pay costs and a decrease of $67,000 for Information Technology savings.

A credible auditing program is an essential and cost-effective tool that P&SP needs to successfully administer the Packers and Stockyards Act. A credible auditing program is one that audits submitted financial information to determine whether: (1) the information is supported by the firm's records, (2) the firm is in compliance with the P&S Act's reporting and financial requirements, and (3) the financial information raises any concerns under the P&S Act's competition provisions. This is why P&SP proposes to do this by establishing a more formal "Task Force to Audit the Annual Reports of the Steer and Heifer Meatpackers," as a pilot program.

Although P&SP's monitoring program results in correcting many bonding and solvency problems, it is critically important to note that P&SP has never audited a large packer. Since the four largest packers account for more than 80 percent of the steers and heifers purchased for slaughter annually, this represents a significant vulnerability in the program's resident expertise. As a result of this, the industry is vulnerable to repercussions that can follow from any incorrect reporting submitted by a large packer, whether or not intentional, that P&SP does not have the ability to address.

To fill this void, P&SP proposes to hire a specialized group of eight staff, consisting of seven accountants and one economist, which will develop a program to conduct these audits within two fiscal years. During the first fiscal year, P&SP will focus on identifying, hiring, and training individuals with the necessary expertise. The training will be obtained from a credible accounting firm with expertise in the meatpacking industry.

Through our increasingly frequent and substantive conversations with industry, we have been able to build relationships that allow us the opportunity to help firms

steer clear of difficulties they may encounter with the P&S Act. Too often, our intervention in a firm's financial difficulties comes at a stage too late for us to protect the interests of the producers. Through a credible audit program, GIPSA can help industry avoid larger problems later on, as well as better protect producers.

P&SP does anticipate that this pilot program will result in a small increase in the number of investigations and an increase in the monies recovered or returned to the regulated industries. But that is not the goal of this proposal. It is not our intent to engage in these audits just to see what we can find. Even if P&SP is unable to show actual monies returned to the industry, the audits are anticipated to result in substantially better financial protection to the regulated industries through heightened scrutiny of the financial instruments that these meatpackers have in place to protect producers in the event of financial failures.

The second increase is for $500,000 to allow GIPSA to engage in a comprehensive internal and external review of the Packers and Stockyards Act and regulations.

The Packers and Stockyards Act of 1921 has not undergone any significant reviews since its enactment, despite substantial and controversial structural changes experienced by the regulated industries during the same time period. To conduct a comprehensive review of the P&S Act, P&SP must incorporate individual industry members and industry groups in the process. P&SP will sponsor industry-wide meetings to hear more about the challenges, concerns, and problems facing those directly involved in the livestock, meat, and poultry industries within the context of the Packers and Stockyards Act.

Packers and Stockyards Programs anticipates that building bridges and reviewing the Packers and Stockyards Act with market participants will result in a better understanding of the P&S Act and regulations by industry, as well as offer the Agency a better understanding of the industry's needs in the changing marketplace. By working with all segments of the regulated industry, P&SP feels it can be better positioned to meet the current and future needs of market participants, and help the Agency become more relevant to current and future industry operations.

In a September 2000 report to Congress by the General Accounting Office titled "Actions Needed to Improve Investigation of Competitive Practices" (GAO/RCED–00–242), a recommendation was included that GIPSA provide industry participants with clarification and views on competitive activities. P&SP responded rapidly to that recommendation, dramatically increasing its presence and participation at industry events and meetings. The requested funds will further allow P&SP to meet this demand for clear, concise information that can be shared with industry stakeholders.

CONCLUSION

Mr. Chairman, Members of the Committee, I would like to conclude my testimony on the fiscal year 2004 budget proposal for the Grain Inspection, Packers and Stockyards Administration with an observation.

Technological advances in new products and in business practices create remarkable opportunities and challenges for producers, marketers, and consumers. GIPSA is uniquely situated to facilitate the marketing of products at a time when assurances of product content or production processes are in demand. Further, GIPSA helps ensure that market power by some is not abused. Responding effectively to the needs of our stakeholders requires dynamic activity.

We continue to adapt our efforts, look toward our capabilities, work to understand and accommodate the changes, and serve American agriculture through our efforts to ensure a productive and competitive global marketplace for U.S. agricultural products.

I would be pleased to address any issues or answer any questions that you may have at this time.

Thank you.

Senator BENNETT. Senator Cochran

Senator COCHRAN. Mr. Chairman, I simply wanted to join you in welcoming this panel of witnesses and congratulating them for the fine work they are doing to help assure that we do maintain the safest food supply in the world. I am convinced they are doing a good job and I am here to find out if the budget request is adequate to enable them to continue their fine work. Thank you.

Senator BENNETT. Thank you very much.

Mr. Bost, you told us that combatting obesity was one of the three main issues you were addressing and gave a statistic that I had not heard before, that 62 percent of Americans are obese. Now, I hesitate to do this, but I am going to do it anyway because I think there is a great deal of confusion, and frankly, it includes some members of this subcommittee. I have mentioned that I am going to do this to some members of the subcommittee and they said, good.

The pyramid that you and—I say "you," I mean the USDA—has been pushing among school children, it is on display everywhere. It is on just about every cereal box that gets sold. It is, if I can mix metaphors a little, the Good Housekeeping Seal of Approval for the way to eat, and it calls for a substantial consumption of carbohydrates.

We have got the Atkins diet that has millions of people believing that carbohydrates make you fat. Recently, the Zone came out. That got introduced in my family and there are members of my family who follow the Zone and have lost substantial amounts of weight as they have cut down on their consumption of carbohydrates.

I have brought along, perhaps as the most provocative one, a recent one that has come to my attention called the Schwartzbein Principle. Not to tout this particular one, but to outline the claims that are being made, lose body fat and transform body composition. Improve metabolism. Prevent and correct chronic conditions and diseases. Reverse accelerated metabolic aging. Quit addictions and food cravings and cure depression and mood swings.

The doctor who started out, as she says in her opening chapters, urging people to follow the food pyramid and discovered that her patients were getting sicker, and then went in a different direction and now attacks the food pyramid as the problem, gives case studies here, admittedly anecdotal, of how cutting back on carbohydrates and increasing consumption of the right kinds of fat and protein did, indeed, all of the things that are listed on the front of this book.

Now, I am not going to in any sense suggest that this is, indeed, the patent medicine to solve all those problems. But coming again and again from a wide variety of folks who look at our eating habits, the assertion that Americans consume too many carbohydrates and that too many carbohydrates are, in fact, responsible for Americans' obesity is something that I think needs to be examined.

Now, you are talking about sending out the pyramid for comment, and I think that is a salutary thing because it implies that you are open-minded about the pyramid and open to further evidence with respect to it. Dr. Murano, you talked about getting the best science possible to deal with food safety, and what I am raising with you here this morning is can we get the best science to deal with this issue of how we eat.

If, in fact, we as Americans have been moving in the direction of the food pyramid starting in the very early years of grade school, and it is included in all of the literature around and Americans do, indeed, go in this direction, and if, in fact, 62 percent of us are

obese, I think there is at least an indication that we ought to look for the possibility of a cause-and-effect relationship here.

As I say, there is a member of this subcommittee, and I will let him speak for himself when he returns if he decides to get into this, who has accepted the notion that carbohydrates make you fat and has himself lost 20 to 30 pounds as he has gone in that direction and says he feels better than he has felt for a long time.

I don't think this is a trivial issue and I don't think it is an issue of fad diets, because there is empirical evidence in the millions of people who have abandoned a high-carbohydrate diet in favor of more protein and more fat in their diet who have, in fact, conquered the obesity situation. Are they endangering their lives? I know there are some physicians who say they are by moving in this other direction.

This is the bottom line of what I am saying. The place where I would like to be able to go to get a definitive answer to this question based on the soundest science, the most comprehensive tests over the widest range of people, so that it is not anecdotal, it is not a doctor saying, "I treated 12 people and produced this kind of result," but a test that stands or passes the challenge of being scientifically sound says, this is the way to eat in order to avoid obesity.

Now, do you have enough budget flexibility to address this kind of challenge and do you have access to the kinds of scientists who would do these sorts of tests, or are these sorts of tests out there so that we can, in fact, turn to USDA and say, you are the final word and if you eat the way USDA says to eat, you won't get fat and you won't get sick. You will improve your metabolism. You will quit addictions and food cravings and whatever and you don't need to buy a fad diet book.

Mr. BOST. Mr. Chairman, this is a highly complex and a significantly difficult issue, but let me respond to some of the things that you talked about. First and foremost, the statistics would indicate that 62 percent of all Americans are overweight. That means over their ideal body weight. Thirty percent are obese. The troubling thing about the 30 percent figure is that it took us almost 15 years to go from 20 to 30 percent. We are anticipating that it is only going to take us about 5 or 6 years to go from 30 to 40 percent which is essentially 30 pounds over our ideal body weight.

Senator BENNETT. Thank you for correcting me on that. I got the wrong statistic.

FOOD GUIDE PYRAMID AND DIETARY GUIDELINES

Mr. BOST. Right. In terms of the Food Guide Pyramid itself, it is a guide along with the Dietary Guidelines—they go hand-in-hand. The Dietary Guidelines are summarized in a book, that has as many as 20 or 30 pages and is currently in the review process. The request to nominations to the Review Board just went to the Federal Register. The Secretary of Health and Human Services and Secretary Veneman will essentially appoint scientists, the leading experts in the field, to start the process now of reviewing the Dietary Guidelines. That process will flow into a review of the Food Guide Pyramid itself, which essentially will come under review the latter part of 2004 and 2005.

With that said, I think it is really important to note that you made reference to three or four different diets. If we go into a bookstore today, you will see hundreds of books in terms of diets, and the thing that it says to me is the fact that one specific diet does not work for everyone. There are some people that talk about the Atkins diet, and that works for some people. That diet doesn't work for everyone.

If you decrease what you eat, increase your level of physical activity, increase your consumption of fresh fruits and vegetables, you will lose weight and you will move toward a healthy lifestyle.

The problem with us as Americans is this. We love to eat. We love a good deal—super-size it. We don't like for people to tell us what to do, and we don't exercise enough. Instead of walking up one flight of stairs, we will catch the elevator. Instead of parking at the farthest parking lot when we go to the mall, we will drive around for 30 minutes to try to get the closest one.

All of those things contribute to the types of health problems that we are experiencing. Last year alone, we spent $117 billion in terms of obesity-related health problems because we are overweight in this country.

There are some steps that we are taking, but it comes down to essentially this. We need to look at doing some things that will result in a behavioral change among all of us, especially among adults who essentially make purchases for our children, so they can provide healthier alternatives in the National School Lunch Program.

In terms of the Dietary Guidelines, they are currently under review. We will bring the best scientists the world has to offer to come to the table to have this discussion and to provide us with recommendations.

But the problem is this, and I use this example all the time when I go around the country and talk about it. We could do a survey this morning in this room and I would guarantee you that at least 95 percent of all the people in this room could answer this question. What has more calories and fat, a doughnut or an apple? But, what are you going to eat?

The issue is us making informed decisions, striking that balance in terms of what we can do to start this issue. It has to be a behavior change. All of the diets that you have, all of the guidebooks, all of the information that USDA provides, all of the information experts provide, is not going to do any good unless we follow it, and that is what it comes down to.

OVERWEIGHT CHILDREN

One final point, and specifically regarding our children. When we look at the statistics in terms of what has significantly contributed to the issues of our children being overweight, it comes down to a couple of things, increased TV watching and increased computer use. There is only one State in the country right now that has mandated physical education in schools K through 12, Illinois. Our kids don't go outside and play and there is a limited level of physical activity among them. They don't walk to school anymore and they eat all the wrong things. As parents, we have to take some responsibility for that because we buy the food that our children eat at

home. All of those factors contribute to the types of health problems that we are experiencing.

I don't want to paint the picture that we are not doing some things and that we are not taking some steps to address this issue because in the National School Lunch Program and the reauthorization of the Child Nutrition Programs, we put some recommendations forward to Chairman Cochran's committee that I know they are considering. But it starts with adults taking some personal responsibility for addressing this issue, and that is what we are trying to achieve in terms of having that behavioral change.

A personal example, 3 years ago, I lost 70 pounds. I could not do the Atkins diet. It did not work for me. I went to a low-calorie diet where I decreased the amount of calories that I took, and increased my physical activity. Not everything works for everyone, and that is why it is called Dietary Guidelines.

In the Food Guide Pyramid itself, it says serving size. There was an article just this week alone talking about the average serving size for some things is less than 2 or 3 ounces, but as an American—the perfect example, and I promise I will be quiet on this, is people say, well, I have stopped eating that doughnut for breakfast. I eat a bagel now. Have you seen the size of bagels in this country?

Five hundred, 600 calories. You are not going to lose any weight by eating a 700-calorie bagel in the morning as opposed to a doughnut. In some instances, it would be better for you to eat the one doughnut.

Senator BENNETT. I can see that——

Mr. BOST. I know more about this subject than I want to know.

Senator BENNETT. I can see that I touched a hot button.

I want to observe the time limit more strictly than I did in my previous hearing, so I will wait for a later chance to follow up, but thank you for your attention to this issue and for your personal passion to see to it that we address it. Again, my only closing comment is I want to be able to look to USDA as the real expert rather than the bookshelf, where there are dozens of experts shouting for my attention. I would hope that the pyramid and the guidelines would be based on the very best information and that people would be open-minded to some of the suggestions that we take a look at how many carbohydrates we do have recommended.

Senator Kohl.

CHRONIC WASTING DISEASE

Senator KOHL. Thank you very much, Senator Bennett.

Mr. Hawks, in February of 2002, chronic wasting disease was discovered, as you know, in Wisconsin deer, and today, we have more than 200 positive cases identified. Last year, this subcommittee provided nearly $15 million in APHIS funding to respond to this disease all across the country, and Wisconsin's share of it was a little bit more than $800,000 out of the $15 million.

Wisconsin officials are in constant contact with us here and they have informed us that they need over $5 million in fiscal year 2004 for continued chronic wasting disease testing and monitoring. Do you intend to respond to their needs? Particularly now with the outbreak of something like mad cow, we understand how important it is to ensure the safety of our animals in this country, and test-

ing, diagnosis, and research, as you know, are the most critical factors here. Money is what it takes to get that done. How do you respond?

Mr. HAWKS. Senator Kohl, I certainly enjoyed being in Wisconsin with you last year and doing a press conference with you there in Madison as this became high on all of our radar screens. As you are aware, we worked with you and other members of the delegation from Wisconsin, with Wisconsin being a high prevalent State, a State that causes great concern to all of us.

We will take the appropriate action, but the amount of funds that we have, the resources, Wisconsin will certainly—we will respond to your needs.

Senator KOHL. I know it is hard for you to be specific and I know how tight money is, but you can expect, and I am sure you can appreciate, how I will be on you and at you with a sense of urgency to try and find some way to increase the amount of funding that we can get in Wisconsin.

Mr. HAWKS. I certainly understand and certainly appreciate that, Senator, and I look forward to working with you. As this Committee goes through the appropriation process, we will make sure that it is appropriately addressed.

Senator KOHL. Thank you, Mr. Hawks.

BSE

Mr. HAWKS. Thank you.

Senator KOHL. To get back to BSE, exporting beef from Canada into the United States is a huge industry up there. In fact, almost 80 percent of the beef that they raise winds up getting exported to the United States for our consumption. So their testing procedures, of course, are critical, and now we have found out that a test that was administered in January finally evidenced a result in May, that there is at least one case up there of mad cow disease. But how they test and how frequently they test, how accurately they test is of enormous importance to us. It is at the same level of importance to us as how we test here in the United States.

So Mr. Hawks, you must have some great concerns about that, and perhaps you do also, Dr. Murano, and I think we would like to hear about your thoughts and what your intentions are with respect to ensuring the American eating public that the beef that is imported here from Canada, which is, as I said, an enormous quantity, is safe. Mr. Hawks?

Mr. HAWKS. Yes, sure, Senator Kohl. We do have concerns which obviously show in the actions that we took just the day before yesterday. From USDA, we have five veterinarians that are in Canada or that will be there today. Four of them is from APHIS. One of them is from FSIS to try to work with our counterparts in Canada to look at their testing protocols and to make sure that we are doing everything we can to assist in this situation.

So we do have those concerns, but the fact of the matter is, here in this country, we feel extremely confident of our testing regimens, our protocols that we have in place. As I stated in my opening comments, last year, we did a little over 20,000 tests on the most likely candidates for BSE, and they were all negative. We are on track to do a few more tests than that this year. Compared to standards

recognized by the Office of International Epizootics, we are testing four times the amount.

So we feel real confident, but also recognize that we must work with our Canadian counterparts to make sure that their testing is appropriate, as well. I will ask Dr. Murano to address the food safety issue because I deal with the animal disease component, so I will get Dr. Murano to answer that.

Senator KOHL. Dr. Murano.

IMPORT REINSPECTION

Dr. MURANO. Senator Kohl, certainly, you know that import inspection, or reinspection, as we call it, of meat and poultry that is imported into the United States is an extremely high priority with us at FSIS.

When this incident happened this week, I will tell you that I was on the phone with our counterparts in the Canadian Food Inspection Agency telling them, first of all, to explain to us what took so long to get that test result, and the basic answer for them is that it was in the pipeline for them to get the sample analyzed. So it wasn't that they held onto it or anything to that effect, but that is not good enough. If they have a backlog with their testing, they have got to do something about it, and if we need to help them, then that is what we need to do. That is on the animal testing.

On testing that we do to ensure that there is no central nervous system tissue in products, they are also responsible for doing that and this is something that I have personally spoken to them about to say, this is something you must do. You must be on top of it. We will lend you all the assistance that we can. If you need us to help you with the training of your laboratory people so that you have more people to do this, whatever it takes is what we will do.

Senator Kohl, in our budget request, for example, for this year, we have requested $1.8 million to increase the number of foreign program auditors from FSIS. It is because of that commitment that we have to ensure that it shouldn't matter where your food came from that is at your table at dinnertime. It is the USDA's responsibility to make sure that the food supply is as safe as possible, and that includes, obviously, making sure that what is imported undergoes the same rigorous oversight and scrutiny as the food that we make for ourselves right here in the United States.

FOREIGN FOOD SAFETY SYSTEMS

Senator KOHL. I would agree, no question as a matter of principle. Would you say, based on all the information you have, that the beef that is imported from Canada undergoes the same safety inspection as the beef that we raise here?

Dr. MURANO. It does, and I can tell you that because we audit their program on at least annual basis, not only in Canada but other countries. We are in Mexico this week, for example, as part of our regular auditing function.

So that is our responsibility, to make sure that these countries that export meat and poultry to the United States have equivalent systems. That means they have to have an inspector in every plant, every day. They have to have a HACCP-based system, which is a preventative system that our meat and poultry plants here in the

United States have to have, with our verification being conducted through microbiological testing and so forth. They have to have all of that the same as we have here in the United States, and they do in Canada.

Senator KOHL. Well, not to pursue it unduly, but we have a testing system that gives us a result in how many days? Mr. Hawks.

Mr. HAWKS. Yes, sir, Senator Kohl. I probably should have responded to that one. Eight days, and we have no backlog, so when——

Senator KOHL. That is great.

Mr. HAWKS [continuing]. We take a sample here, we get the result within 8 days.

BSE TESTING

Senator KOHL. But they apparently have a testing procedure that yields a result in several months? Or is there something here that we are not tracking?

Dr. MURANO. No, as I was explaining, and Mr. Hawks can tell you more, the test that you are referring to is on the animal. It is not something we do at FSIS. It is akin to the APHIS surveillance that they do on animals.

So my understanding from the Canadians is that they had a backlog of samples to analyze. It is not that their test is any different than ours. It is the same test. But their backlog caused their delay in having that sample collected in January, not analyzed until now.

Senator KOHL. But that kind of a backlog would not be tolerated by you here.

Dr. MURANO. No.

Senator KOHL. So that the fact that they have it up there is as intolerable as it would be if it were true here in the United States, because as I said, 80 percent of the cattle that they raise winds up being exported to us. So whatever problems they have are our problems, isn't that true?

Dr. MURANO. I think you are absolutely right. The testing of the products, of the meat and poultry that I referred to, they have the same systems that we have, with no backlog. This is a testing of the animal, and I will defer to Mr. Hawks to get his comments as to what he believes in terms of their programs in animal health, what should be the equivalence that is expected of other countries.

Mr. HAWKS. Yes, sir. I think they have adequate testing in place, but obviously, this cow was actually slaughtered on the 31st of January. The conditions of the cow—it was not suspected, it was not showing neurological signs—so it was a routine surveillance method.

Having said that, I will back up and say again that we do our routine surveillance within 8 days of the sample being taken. So it is something that obviously we should be addressing with our counterparts in Canada.

Senator KOHL. Thank you. Thank you, Mr. Chairman.

Senator BENNETT. Thank you. Senator Cochran?

FSIS BUDGET REQUEST

Senator COCHRAN. Mr. Chairman, I am impressed with what we have heard this morning, particularly with respect to food safety issues. I am interested to know, however, whether or not the budget request is going to be sufficient for us to continue to maintain the high-quality procedures and processes that we now have in place and are using to ensure that our food supply is safe and wholesome and fit for human consumption. Mr. Bost, I guess we should ask you that, or Dr. Murano.

Dr. MURANO. Certainly, Mr. Chairman, you know that this 2004 budget request is really a record-level increase in our budget that the President is requesting. It is $42 million over what we had before, and so in these times of budgetary constraints and fiscal conservatism, if you will, it shows a commitment of this Administration that we are putting so much importance in food safety that we are asking for record level funding for the Food Safety and Inspection Service.

It has to do not only with adequately being able to pay the salaries of our inspectors, who do the work of food safety out in the field and are the ones who deserve all the credit for our accomplishments.

But also, we are requesting money to conduct baseline studies, to continue the science-based policy making that we have been undertaking over the last couple of years and money to really overhaul the training of our inspectors, which is very much needed. That is money that is so crucial to have because it will ensure that our inspectors continue to be the best trained and that they continue to avail themselves of the state-of-the-art knowledge in food safety implementation so that they can continue to do a good job. We are also requesting money for additional microbiologists and laboratory personnel so that we can continue to do all the work that needs to be done in laboratory sample analysis and so forth.

So, we are very confident that these requests are certainly what we need to meet the challenges that I mentioned in my opening remarks.

Senator COCHRAN. Thank you.

FOOD SAFETY

Mr. BOST. And Senator Cochran, let me add to that. We all have a very important part of the food safety picture in this country and we want to ensure that all the food, that is supplied to our school children is safe. For my piece of it, by the time we get it, most of the issues are directly related to the handling of the food itself.

As I testified in front of you, I guess about a month or so ago, what we want to do is to ensure that staff who work in the National School Lunch Program receive a high level of training so that they can ensure that the food that they receive remains safe. And so our request is to ensure that we do that. We believe that we have the resources to do that. We can always—I am not going to say that you ever have enough, but we could always use more, but we think we have adequate funding to start that process for food safety persons.

Senator COCHRAN. Mr. Hawks.

Mr. HAWKS. Yes, sir, Senator Cochran. It is certainly a pleasure to be here and to respond to questions from a friend from Mississippi. We feel like this Committee and this Congress have been extremely generous with us over the past 2 years. Since coming here for the supplemental defense appropriation, we were able to take those funds to improve our laboratory conditions, to improve our surveillance methods. We were able to work with the States. So we think that we have adequate funding. The President's budget is adequate to continue this process.

I would like to, if I may, take the time to go back just a little bit to the BSE and say that, for the record——

Senator COCHRAN. Can you tell us how to pronounce what that stands for?

Mr. HAWKS. Bovine spongiform encephalopathy, you have got it, Senator. I pronounced that in Paris on Sunday and my staff that was with me told me that I need to practice, so I have been practicing before coming here today.

But that particular animal did not go into the food chain. While there was a delay in testing, that animal did not go in the food chain, so I think that is important for me to point out. It's just an oversight on my part earlier.

Senator COCHRAN. Thank you very much. I appreciate the good job you continue to do, as well.

Senator BENNETT. Senator Johnson?

CANADIAN LIVESTOCK PROHIBITION

Senator JOHNSON. Thank you, Mr. Chairman.

Would it not make sense to maintain the prohibition on Canadian livestock and meat exports into the United States until the United States can be comfortable that they have eliminated their backlog and that their inspection regime is essentially on a par with that in the United States?

Dr. MURANO. Well, Senator, let me make sure that everybody understands. Their inspection of products, beef and poultry products, is the same as the United States. The issue at hand here is on the live animal, and the animal disease surveillance program that they have. And certainly, we need to make sure that there is no question in anybody's mind as to whether all the facts have been ascertained in terms of any cases of BSE anywhere in the world, Canada, or any other countries.

And so I will venture to say that the Secretary of Agriculture will certainly be very cautious in lifting that ban. She will take all the information that is available as it comes in terms of the samples that are still in the backlog and other information that is appropriate and will not do anything until she is confident that it is safe to lift that ban, and I will guarantee you that that is exactly what she is thinking.

Senator JOHNSON. Well, it concerns me that they may use the same science ultimately as we use in the United States, but if there is a 4-month backlog in this particular instance, that gives rise to great concern that what would have happened if that animal had been exported into the United States during that interim period.

Dr. MURANO. Well, that animal would not have, because remember, it was an animal that had pneumonia and when the animal was put down, the normal thing that happens, just like we do here in the United States, those animals are condemned. Any animal that is diseased is not allowed in the food supply, whether it is BSE, pneumonia, or anything. So that animal would not have entered the food supply anyway. It just so happens that as they tested it, it came out positive for BSE.

Senator JOHNSON. When we say the animal is not in the food supply, just so I understand this, it is my understanding that the carcass of this animal was, in fact, ground up and used as animal feed. Is that correct or not correct?

Dr. MURANO. I understand, that it did not enter the human food supply. So let me allow Mr. Hawks to tell you more about that.

Mr. HAWKS. Senator, I am under the impression that that animal, as we said, did not go into the food chain. I would have to clarify what actually happened, in the rendering process. So I apologize for not having that answer.

Dr. MURANO. But it certainly did not——

Senator JOHNSON. One of my concerns would be if that did, in fact, wind up as animal feed, that, in turn, then, was—whether there are animals that could have fed on that.

Dr. MURANO. I follow you, and that would not happen because Canada has a feed ban, just like we do.

Senator JOHNSON. All right. I appreciate your response here. It would appear to me that because of the 4-month backlog, however, our Canadian friends have some work to do——

Dr. MURANO. Yes, they do.

Senator JOHNSON [continuing]. In order to allow our consumers to have the confidence they deserve to have, and I would hope that our USDA will be very aggressive in working with Canada in that regard.

COUNTRY OF ORIGIN LABELING

Mr. Hawks, on the country of origin labeling issue, in general terms, the United States only imports around 2 million head of live cattle but slaughters 28 million head. Obviously, most of the cattle we slaughter are of U.S. origin. Doesn't it make sense to USDA that tracking of 2 million imported cattle would be less costly than keeping track of the 28 million within the United States?

Mr. HAWKS. Senator, I certainly understand your question, and having been through several of these country of origin listening sessions, I will say to you that I am committed. I will personally be at those sessions, or my Administrator of AMS will be at every one of those to listen and to hear the comments.

But to be very candid with you, it is the assessment of our attorneys that we could not do that as the law is written simply because it requires all products to be labeled with country of origin. So the law does not allow us to do that, as written.

Senator JOHNSON. It would seem—many of my constituents have suggested if you label imported animal, then it is obvious that the other animals are, in fact, United States animals.

Mr. HAWKS. That is understood, but as we have had numerous sessions with our attorneys to help us interpret the law as written,

it requires every product in the retail market to be labeled. And then it is the specificity of the law—born, raised, and slaughtered. It is giving us great difficulty to look at it from that perspective.

Senator JOHNSON. The country of origin labeling law gave USDA discretion to create an audit verification system, but not a mandatory system, to help verify the origin of livestock. We included many existing industry practices and USDA programs to model in order to achieve voluntary audits. Some of these models include the USDA grade stamp program, that is to say, "choice," "select," et cetera, "certified Angus beef" and other breed programs, beef quality assurance, Hazard Analysis Critical Control Points, HACCP, the National School Lunch Program, the Market Access Program, and the voluntary born and raised in the USA label used by Carolyn Kerry of California.

To what extent is USDA looking at using these existing models rather than reinventing the wheel to implement country of origin labeling?

Mr. HAWKS. Senator, as I said, as we go around the country, we are listening to all of the concerns, the issues that are being raised. So we are evaluating everything that is out there. However, the requirement is a retail labeling law, so it is controlled more from the retail, and the law also goes on to say that everyone that is supplying product into that retail market is required to provide the verifiable information as to the country of origin.

So we will be continuing to look at all of these and try to come up with something that is reasonable, but it is actually the retail market that is going to drive that.

ANIMAL IDENTIFICATION

Senator JOHNSON. Would you agree that the law prohibits on-farm mandatory animal identification and does not permit third-party mandates by packers?

Mr. HAWKS. I will agree that it absolute prohibits mandatory identification for the purpose of country of origin labeling. As to the third-party audits, I would say that that is a proven practice. It is something that is not unreasonable and I would say the retailer would have the right to require that in that case.

Senator BENNETT. The time is expired——

Senator JOHNSON. My time is expired. I will continue with some other questions and we may submit at a later time, as well. Thank you, Mr. Chairman.

Senator BENNETT. We can come back to this. I want to pursue this same question on a quick second round because I think Senator Johnson is focusing on one of the most contentious problems we deal with. A number of producers are in favor of a system that would allow farmers to self-certify. In your opinion, is self-certification legal?

Mr. HAWKS. In my opinion, self-certification in and of itself would not fulfill the requirement.

Senator BENNETT. Congress made the law. Congress can unmake the law. If we should amend the law to allow self-certification, do you think that would be adequate to achieve the goals that we are looking for here?

Mr. HAWKS. Senator, as you say, Congress makes the law. It is my job to implement it. So as you move forward, any decisions that you make, I would be happy to work with you to help implement those provisions that you put in.

Senator BENNETT. You are beginning to sound a little bit like Mr. Greenspan who testified before us yesterday at the Joint Economic Committee.

But let us assume that Congress changes the law and allows self-certification. Do you have any idea of how farmers' would handle animals that are commingled?

Mr. HAWKS. The animals that are commingled would cause a real serious problem as I see it. If you have animals coming in from Canada, if you have animals coming in from Mexico and then you have a self-certification, I think it would be very difficult because it is ultimately the farmers responsibility to provide that chain of custody, that information up through the system to the retailer. So it could potentially be problematic.

Senator BENNETT. And the $10,000 fine per violation, it is the retailer, not the——

Mr. HAWKS. The fine would hit the retailer, that is correct, but that fine would also fall back on the supply chain as you go up, as well, because the law also requires those in the chain to provide information to that retailer—it actually mandates that they provide that information to the retailer. So then they would be subject to fines, as well. So it is sort of like a domino effect.

Senator BENNETT. I see. So the retailers probably would not accept self-certification?

Mr. HAWKS. It would be probably difficult. If I was a retailer, I would be very cautious in accepting that.

Senator BENNETT. Okay. Thank you.

Does anyone else want a second round on this panel?

FRESH FRUIT AND VEGETABLE PILOT PROJECTS

Senator KOHL. I would just like to ask Mr. Bost one quick question, Mr. Chairman. Mr. Bost, the 2002 farm bill provided $6 million for a fresh fruit and vegetable pilot program for the 2002–2003 year. The program provided fresh fruits and vegetables free to children in 107 elementary and secondary schools across four States. Preliminary evaluation of the program by USDA indicated that it was a very successful program and that, overwhelmingly, the schools hope that it could be continued as well as expanded to other schools. Do you have plans to do that?

Mr. BOST. The formula, as you noted, essentially provided us with the authority to do it this year and it was supposed to end. I believe that both the House and the Senate have approved an extension of the $6 million that was appropriated, so the program will go on until it is complete.

As a part of the Child Nutrition reauthorization, as I testified in front of Chairman Cochran about a month or so ago, we are looking at the possibility of extending these pilot projects in those existing States and also adding two or three additional States. The question is going to be where we get the money from. It was very well received by administrators, educators and teachers. The children loved it. It has been one of the most successful nutrition programs

that we have implemented since I have been Under Secretary in terms of the positive feedback that we have received.

In addition the program is also being implemented and carried out on one of our Indian reservations, and very well received there, too.

Senator KOHL. If you are as enthusiastic as you say you are, and I believe that is true, I would like to work with you to see that we get some additional funding, not only to continue with the program but to expand it and grow it.

Mr. BOST. We are always happy to work with you.

Senator KOHL. Thank you.

Mr. BOST. Thank you.

Senator BENNETT. Senator Johnson, do you want to——

Senator JOHNSON. No.

Senator BENNETT. Thank you all. We appreciate, again, your testimony and we appreciate your willingness to render public service to the citizens of the country.

Mr. BOST. Thank you, Mr. Chairman.

Dr. MURANO. Thank you.

Mr. HAWKS. Thank you.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

STATEMENT OF HON. MARK B. McCLELLAN, COMMISSIONER

ACCOMPANIED BY JEFFREY WEBER, ASSOCIATE COMMISSIONER FOR MANAGEMENT AND SYSTEMS

Senator BENNETT. We will now proceed to hear from the Commissioner of the Food and Drug Administration, who has been very patient with us listening this morning.

We are happy to welcome the Honorable Mark McClellan, who is the Commissioner of Food and Drugs, accompanied by Jeffrey Weber, the Associate Commissioner for Management and Systems at the Food and Drug Administration.

Mr. McClellan, thank you very much for your willingness to sit through the earlier conversation. I am grateful to you for your willingness to do that. I think given the concern about food and safety that is currently highlighted in the news, it is important that we demonstrate that FDA and USDA are both on the same page. We need to have something of a calming effect, if we can, on some of the hysteria that seems to arise whenever the media gets something of this kind.

Thank you for being with us and we look forward now to your testimony.

Dr. MCCLELLAN. Thank you, Mr. Chairman. I am happy to be here. I enjoyed the opportunity to sit with very capable staff from USDA that we work with very closely.

It is a pleasure to be here with you today, Mr. Chairman, Senator Kohl, Senator Johnson, for my first Senate Appropriations hearing on FDA's budget, and I understand it is your first as Chairman of the subcommittee, as well. Hopefully, this is the start of a great new tradition. I am sure that you are enjoying your new responsibilities as much as I am enjoying mine. We are all making a very real difference in people's lives.

FDA is a vitally important public health agency. All Americans have long depended on us to have confidence and the safety and security of many products they use every day and many that they depend on for improving or even saving their lives.

Mr. Chairman, you have a detailed statement for the record. This morning, I would just like to highlight some of my top priorities for the agency. These priorities are from the FDA's new strategic action plan, which reflects the ideas of our own staff, the public health priorities of the Secretary and the President, and special concerns that I have heard about from many of you and your very capable staffs.

First, to do the most effective job possible, FDA must base its regulatory work on the principle of efficient risk management. That is kind of a mouthful for a principle, but the idea is to use the lat-

est biomedical science and risk management science to find the best ways to reduce the risk facing the public and to do it as efficiently as possible. Since our challenges and the new opportunities we face are greater than ever, this use of up-to-date science is essential in enabling the agency to fulfill its mission.

We are regulating more and more complex food products than ever before. Over the past decade, the number of food import shipments has increased more than four-fold. We are expecting over six million shipments in 2004. Americans are eating more diverse fresh, uncooked products than ever, and we have got to focus not just on the safety of our food supply, but on its security against deliberate attack.

We are facing a broader array of more complex medical products than ever before. The traditional distinctions between drugs and devices are breaking down as we see more products that include both. The traditional methods of bringing blockbuster drugs to market are in the process of being replaced with more sophisticated methods based on new breakthroughs in genomics and proteomics that will lead to more individualized patient treatments in the years ahead. The doubling of the NIH budget over the past 5 years promises the development of even more valuable treatments going forward.

The products that we regulate, including foods and medical treatments, are increasingly important in international trade negotiations and in steps to make the global markets for medical products more efficient. This is all potentially very good news for Americans. More diverse and innovative products hold the promise of better, longer, more fulfilling lives, but that promise will only be fulfilled if the agency continues to fulfill its responsibilities to help make sure that all of these products are safe and can do what they are supposed to do.

As we face these increasing responsibilities, it is critical for the agency to get the most out of our limited resources through regulatory processes that do as much as possible to reduce the risk facing the public and to get the most bang for our regulatory buck. Recent legislation supported by your appropriations in the 2003 budget provide new opportunities for us to do this through our expanded food security authorities and personnel, through newly implemented legislation on pharmaceutical and medical device user fees, and through other new initiatives on such critical topics as patient safety. We owe it to the American public to make the most of these new opportunities.

We are seeking to improve the quality and efficiency of the process of developing new medical technologies. We are also conducting a major overhaul of our oversight of the processes that medical manufacturers rely on to help ensure that medical products are safe and effective and of high quality. We are implementing a new risk-based import security strategy. We are taking new steps on many other pressing issues, ranging from bioengineered products, to dietary supplements including ephedra, to generic drugs, to veterinary medicines, in all cases using the best science and our statutory authorities to make sure the agency is having the maximum impact on the public health that is possible under the law.

At your request this morning, I want to add some remarks about bovine spongiform encephalopathy, BSE. It is a good example of our use of risk management techniques quickly and effectively to be prepared for new public threats. Since the early days of this disease, FDA and USDA have worked aggressively to protect Americans from BSE and to develop and evaluate contingency plans for further developments in the course of the disease. With the most recent news of a single BSE-positive cow in Northern Alberta, we are responding immediately with additional steps for the protection of the American public.

These include, first, adding Canada to the list of countries in FDA's import alerts related to BSE. Under these alerts, FDA stops a wide variety of products, such as animal feed and human food with bovine-derived materials from being imported into the United States from BSE countries.

Second, we are using the FDA's BSE response plan, which has already been developed, for guidance on responding to this threat quickly and effectively.

Third, we are communicating closely with Canadian officials. We have offered to send FDA experts to Canada, as well, to assist them in their investigation and to learn from this case. As we learn more of the facts of this incident in Canada, we will continue to act promptly to assure that scientifically-appropriate safeguards in place in the United States will protect the public health as effectively as possible.

As you know, BSE does not spread naturally from cow to cow. Instead, the infectious agent is passed only when a BSE prion-infected protein from a rendered BSE-infected animal is added to animal feed and subsequently fed to cows. So fourth, and most importantly in our response, our animal feed rule prohibits the use of most mammalian protein in feeds for use in ruminant animals, such as cow. This rule has become one of the essential firewalls against the spread of BSE in the United States, as Senator Johnson noted. Even if an infected animal were ever to be found in the United States, and none have been, this rule would prevent the spread of the disease.

In the past several years since the data was collected that the GAO report relied on, the report that Senator Johnson mentioned from 2002, we have taken a number of steps to respond to the concerns raised there. I agree with you, Senator Johnson, that we need to be extremely vigilant on this issue.

So we have ramped up our inspections of animal feed manufacturers, feed mills, all other firms responsible for keeping—that use ruminant protein to make sure that it stays out of cattle feed, and at this point this morning, I can report to you that we have 99.3 percent compliance. That is 0.7 percent of the inspections of all of these firms, this entire universe of firms handling the bovine material related to feed, that may be out of compliance, and for those small fraction that are out of compliance, we are following up very quickly. We have had follow-up visits within 30 days to these firms. We have issued 59 warning letters involving 42 product recalls involving 241 products.

So we are very much concerned with making sure this program works effectively. We are spending $22 million on this program this

year. Our inspectors are working with the States closely. We have conducted a number of training sessions. We have developed a standardized form. We are implementing checks to make sure that all of the inspectors doing these activities, the Federal inspectors from FDA as well as our State partners, are following consistent and appropriate procedures in their inspectional activities.

And just to be clear, these inspections cover all of the issues that you raise. There can be no commingling of materials, no mislabeling of foods containing prohibited materials in order for a firm to be in compliance, and we expect 100 percent compliance. We are pushing and aiming for full compliance. We are inspecting every plant every year to make sure they are in compliance and we are doing rapid follow-ups on the small number of plants that are not.

Our work on BSE underscores the fact that FDA is, above all, a public health agency. So let me mention again a few of the other top priorities here at FDA.

One of these areas is patient safety, preventing adverse events. Improper use of pharmaceuticals alone accounts for thousands of deaths, millions of hospitalizations, and many billions of costs and avoidable medical complications each year. FDA has recently announced a set of new programs to reduce preventable adverse events involving the products that we regulate, and that includes preventable food illnesses and reactions as well as medical adverse events.

A third priority for us is getting better information to consumers about how they can improve their own health, and you all have already touched on that in the previous panel this morning. We all know that informed consumers are our greatest public health asset. By making the right decisions, individual Americans can do more to improve their health and their quality of life than the newest medical technology can do for them overall from a public health standpoint, as powerful as those new technologies may be. And we are taking many new steps to help the public get the best science-based information about the health consequences of the products that we regulate.

The fourth priority involves protecting the country against terrorism. There is no challenge more urgent in this post-September 11 world than to engage in the steps needed to protect our citizens from deliberate attacks that may involve the food supply and to provide good medical countermeasures for the agents of terrorism. We are putting in extra hours in many of our medical products centers to make available safer, more effective treatments and prevention methods for biological, chemical, and radiological attacks. We are also an integral part of the President's proposal for Project BioShield to create the next generation of better, safer medical countermeasures as quickly as possible.

Of course, our largest anti-terrorism program involves the security of our food supply. Through new statutory authorities and new regulations that we are in the process of issuing right now, as quickly as possible, and new personnel as well as new strategies to make our food supply not only safer, but more secure, we are trying to provide a new level of security for the American food supply against deliberate kinds of attacks on it.

Finally, the most important resource our agency possesses is its talented and dedicated professional staff. Some of our most important dedicated professionals are with me here this morning a couple rows behind me. There are some new faces in our program. There is Jeff Weber's face, which is not new but is a very effective one in working with us and working with your Committee. We are working hard to attract support and retain highly qualified professionals in order for the agency to be able to adapt and carry out all of the activities that I have outlined. We need to provide the most public health protection for every public health dollar invested and our staff is the first and the most important part of fulfilling that mission.

So I appreciate your attention this morning to FDA. I can assure you that the priorities that we discuss are going to guide our agency's actions during my tenure as Commissioner. We have a budget request of $1.7 billion to support these top priorities as well as our other safety and security mission activities. It includes a set of proposals, new initiatives that I won't go through in any more detail now. You have got them in front of you.

But I want to conclude by saying that I very much look forward to continuing to work with this subcommittee to achieve our mutual goal of moving FDA forward, because that is so important for protecting and promoting the health of Americans. Thank you for your time this morning.

PREPARED STATEMENT

Senator BENNETT. Thank you very much and for your response to the issue that we discussed in such detail with the first panel. That is very helpful.

[The statement follows:]

PREPARED STATEMENT OF MARK B. MCCLELLAN

Mr. Chairman and distinguished members of the Subcommittee, I am honored to be with you today as we discuss FDA's 2004 budget request. I want to thank you for your interest in the Food and Drug Administration and to reaffirm the importance of the FDA and its enormous contribution to our nation's health.

As a practicing internist and a former professor of both economics and medicine I was well aware of the importance of the FDA and its enormous contribution to our nation's health. Now, as the Commissioner of FDA, I have quickly come to understand that ensuring adequate and properly targeted resources is vital to the continued success of the agency and the success of the President's efforts to promote quality health.

I find it a rewarding and exciting time to be at the FDA. The challenges we face in promoting and protecting the public health are greater than ever. The agency is charged with regulating activities which have increased in volume and complexity, a trend likely to continue. There are additional drugs and medical devices available to save and improve lives, and even more to come. There are increasingly diverse food products—giving consumers more food options to meet their needs more productively than ever. And we are adding to these choices by importing a larger volume and greater diversity of foods than ever before. There are also broader choices in cosmetics.

The result is, Americans have more opportunities to improve and enjoy their lives—and these are good things for Americans. At the same time, however, they present unprecedented challenges for FDA in meeting our regulatory responsibilities. Even as the complexity of these products increases, we must continue our commitment to making sure safe and effective new food and drug products reach consumers in a timely fashion. We have responsibilities over 20 percent of the consumer economy—an amount that's growing every year. All of this has immensely complicated FDA's mission. The FDA also must think critically and carefully about

how it uses its resources to improve the public health. Mastering this great responsibility in the 21st Century requires FDA to meet some unprecedented challenges.

I believe there are five major steps we need to take to conquer the challenges we face. A strong FDA that attracts and retains the most talented scientists; dynamic and responsive regulation utilizing new and better ways to reduce risks to the public health; promoting quick access to new medical technologies that are safe and effective thus helping to reduce adverse events involving FDA-regulated products; helping consumers get truthful and non-misleading information about the products they use; and, quick responses to the more pressing challenges of bioterrorism and food security. These are among the many critical steps the agency must take as it looks forward into the 21st century. I would like to first cover the challenges and our strategic planning effort, which include these steps, and then will discuss the specifics of FDA's budget request.

Strategic Planning

To meld it all together—the new challenges, the new opportunities and the steps to be taken, we have undertaken a major strategic action plan within the agency utilizing creative thinking from inside and around the agency we have undertaken a major strategic action planning effort. Under the leadership of FDA's Executive Council we established five broad strategic goals to frame the Agency's future. FDA's leadership is now finalizing a strategic framework to identify objectives and strategies within each of these goals. Cross-cutting work groups, led by members of the senior management team, were established for each goal area. Each group initiated its work based on the Secretary's and my priorities, proposed initiatives, and a broad range of objectives and strategies that are already underway or proposed in recent planning initiatives. Our steps have included leadership development of agency strategic objectives; development of the long-range strategic plan based on the framework; and translation of the strategic plan into a specific action plan for the remainder of fiscal year 2003 and 2004. This effort encompasses the 5 critical challenges and lays the foundation for our action plan. I look forward to discussing this with you as this effort matures. Now lets review the steps we are taking to address the challenges ahead.

Strong FDA

The critical challenge for a strong FDA remains. Essential to the success of the agency is its professional workforce and their ability to maintain a high level of public trust in FDA's activities. Two-thirds of the money we're appropriated each year is spent on our highly-skilled workforce to carry out FDA's complicated mission. Our contributions are primarily a reflection of our professional services.

An organization that can keep up with the rapid changes in the industries it regulates, and one capable of developing and implementing effective and innovative public health measures, requires a very special workforce. So our mission depends more than ever on a solid cadre of experienced physicians, toxicologists, chemists, statisticians, mathematicians and other highly qualified and dedicated professionals. Their expertise is essential for making our regulatory decisions balanced and fair, and for keeping us on the cutting edge of the technology and sciences used by industry. A clear sense of mission is not enough to attract and keep the best and brightest, highly motivated employees who are essential to meeting the challenges that the FDA faces in the 21st century. As FDA Commissioner, it is one of my foremost goals to make sure that the FDA's working environment encourages creativity, efficiency, and superior performance—an environment which attracts and retains top-quality scientists, and enables them to do top-quality work as part of an effective team.

To attract and keep high-caliber employees who are responsive to the changing needs of the agency, we need to be responsive to their diverse needs. FDA is already leading the way with many such workforce initiatives already. Our employees can take advantage of flexible work schedules, including an "any-80" program that can fit the difficult schedules of two working parents, sick kids and sick parents, and other outside commitments. About one-fifth of our employees take advantage of our flexi-placing program, which permits telecommuting. And we support employees with child care, elder care, and other distinctive needs.

In a recent survey conducted by OPM to gauge how Federal employees feel about their jobs, FDA did very well compared to other government agencies and the private sector, especially in how our employees feel that their individual work here relates to Agency's core mission. About 73 percent said that they found FDA a friendly place to work, 82 percent said their supervisor supports their need to balance work and family issues, and 65 percent said they would recommend the FDA as a place to work. We're doing well. We want to do better.

We must reward employees who distinguish themselves and who remain committed to our agency despite attractive outside job offers. On the one hand, I'm glad that so many of our employees have other good options. That tells me that we are attracting very talented people. On the other hand, I don't want to lose them. We therefore offer a range of programs to help recruit and retain talented staff, including expansions of retention bonuses for employees in fields with a particularly high turnover. In collaboration with the National Treasury Employees Union, we are also working to provide additional financial rewards for high performing workers

FDA must encourage fresh perspectives and plan for transitions as well. For some of our workers, spending time here as well as in academics or industry is the most rewarding career path, because it is the best way to keep up with rapid scientific change. And more than 30 percent of our workforce will be eligible for retirement in less than 5 years. So we are working to develop succession plans and career development plans. And we are expanding career options, such as new fellowships and part-time appointments at our devices center, to support combining work at FDA with work in an academic agency.

We will continue to find better ways to support our work environment. The enormity of our task also compels us to seek new ways to augment our available resources. One such opportunity is to use the accumulated experience of FDA alumni. I'm very pleased that scores of alumni from around the country have come together to establish the FDA Alumni Association. The FDAAA can offer much to help us meet our challenges.

Risk Management

Second, to strengthen our agency's ability to meet the challenges of food and drug regulation in the 21st century, we must rely on the best science available. Risk management is one of the many areas of regulatory science FDA has long used in addressing risks to public health and finding the best science for managing them. We must use creative thinking and science-based risk management to increase public health benefits while minimizing the public health risks. We must work to ensure that our regulations and our decisions are firmly anchored in the latest science; that they are fair; that they are dynamic; that they are focused on public health risks; that they are cost-effective; and above all, that they are responsive to the changing circumstances we face.

We must do all we can to ease the regulatory burden. We need to adjust our policies, methods and practices to the increasing volume, variety and complexity of products under our purview, as well as to increased threats—such as bioterrorism. We have to broaden the application of the science of risk management through a committed, constant and consistent effort to find ways to reduce health risks and increase health benefits to the public as efficiently as possible.

Earlier this year as part of our response to this challenge—to make sure we have regulatory processes that are as efficient and up-to-date as possible—we announced a major new medical technology development initiative with three main elements. The new initiative includes a detailed plan for an overhaul of the practices on which the FDA as well as manufacturers rely on to ensure that pharmaceutical products are safe. The new initiative will encourage manufacturing innovation while continuing to assure the highest drug quality.

First, we are conducting a "root cause analysis" of recent "multiple cycle" product approvals—products that required two or more "rounds" of review before they could be approved. An extra round means at least an extra 10 months or more, which can add many millions to the cost of new products. It also delays availability to patients who might benefit from the product. Second, we are developing "quality systems" for our review procedures. The idea is to apply best management practices internally to our review processes, such as using peer review programs for reviewers to exchange ideas and use each others' experience to learn about best practices. Third we will work to publish new guidance documents. These new guidances will be in areas we think the regulatory pathways could be improved or better defined. We expect to learn something from outside experts in the open process of developing guidances. The new guidances will include product guidances for treating obesity, diabetes, and cancer. We think that new regulatory standards can reduce the time and cost of product development.

We are already advancing changes that will help us achieve these three new goals. For example, we have developed a detailed plan for an overhaul of the practices on which the FDA as well as manufacturers rely on to ensure that pharmaceutical products are safe. GMP policies haven't been updated in 25 years. Meanwhile, best practices in manufacturing technologies and methods have undergone significant progress over that time. We are developing new GMPs based on the latest science of risk management and quality assurance. The new standards are being

designed to encourage innovation in manufacturing and technology; coordinate submission review and inspection programs; and ensure their consistent application by all three FDA centers that regulate pharmaceutical products. This includes new guidance from CBER on the manufacturing requirements for novel technologies such as cell processing and gene therapy operations. The medical device user fee act also significantly expands FDA's informal policy of allowing third parties to conduct facility inspections under more closely supervised conditions, to give some manufacturers the flexibility to have their inspections carried out more quickly without sacrificing stringent safety standards.

For food, there are several issues that are very much at the center of our attention. One of them is ensuring the safety of genetically modified feed and foods, and strengthening the public's confidence in these new products. Genetically engineered crops are increasingly common Field tests of new plants in the United States have increased more than eight-fold in the last 8 years, and bioengineered crops are now grown on 130 million acres world-wide. The public's concern about these food products is also strong, as was recently illustrated by the media coverage of the commingling of small amounts of bioengineered corn with soybeans that had been intended for consumption.

In the last 10 years, the FDA has evaluated more than 50 new varieties of bioengineered plants submitted to our agency. The basis of this cooperation was an FDA policy, supported by the industry, of voluntary consultation before the biorengineered products are marketed. To help expand similar protections beyond the U.S. borders, FDA's scientists have worked with the Codex Alimentarius Commission of the World Health Organization/Food and Agriculture Organization, WHO/FAO to draft guidelines for the assessment of safety of foods derived from rDNA plants. And to get the best outside advice on food biotechnology issues, the FDA has established a new Food Biotechnology Subcommittee of its Food Advisory Committee.

Currently, as part of a project organized by the White House Office of Science and Technology Policy, we are preparing draft guidance for industry to provide early food safety evaluations for new proteins in bioengineered crops for food or feed. If developers establish that these new proteins are safe for consumption—meaning, that they do not raise questions about their allergenicity and toxicity—then the foods containing low levels of these innovative plants could be marketed without comprehensive review. We will remain vigilant in addressing concerns about genetically modified food and feed.

Next, I want to bring you up-to-date on the FDA's progress in addressing an issue that has stirred great interest among food scientists. I am referring to the studies released that show that baked, fried or roasted foods rich in carbohydrates—including such dietary staples as bread—contain acrylamide, which, at high doses, is a known animal carcinogen. In soft bread, the reported levels of acrylamide range from 30 micrograms to 162 micrograms per kilogram, and in potato chips, to mention another example, the range is from 1.4 micrograms to 100 micrograms per ounce.

Acrylamide is well known to manufacturers who use it for water treatment and production of dies and plastics, but it is largely a terra incognita for food scientists. Given the key role of carbohydrates in our diet, it's been incumbent on our scientific community to subject acrylamide to a close scrutiny. Some of the questions that need to be answered are, for example, is it genotoxic? How is it formed? What is its level of exposure in the general population? What is its bioavailability in food? And what are the biomarkers of acrylamide exposure? And, what steps can be taken to reduce the levels of acrylamide in food?

FDA is making a significant contribution to this research. Our agency has developed a method for measuring levels of acrylamide in foods, and used it so far on about 300 types of products, including cereals, breads, and chips. We're developing an understanding how acrylamide is formed, which is very important for finding ways how to keep it out of food; and we are probing the chemical's toxicity. Recently, we reported these and other findings to our Food Advisory Committee.

With regard to chronic wasting disease, CWD, it has now been found in farmed or wild deer and elk in 12 states and two provinces in Canada. CWD belongs to a group of transmissible spongiform encephalopathies, or prion diseases, which also includes BSE in cattle, scrapie in sheep and goats, and classical and variant Creutzfeldt-Jacob diseases in humans. There are currently no vaccines or treatments available for these diseases which are invariably fatal. Compared to other TSEs, CWD spreads readily between susceptible species. However, because CWD's route of transmission is poorly understood, there is considerable uncertainty whether CWD poses a threat to humans or livestock is high, also not be used in animal feed.

In order to minimize any risk to public health, FDA publicly announced last November that material from CWD-positive animals should not be rendered for use in feed for any animal species. FDA further recommended that animals from positive captive herds and animals from high risk areas, such as those parts of Colorado, Wyoming and Wisconsin where the prevalence of CW is high, also not be used in animal food. FDA is also collaborating with other Federal agencies in studies of the risk of CWD in the food supply, and the transmissibility of CWD to humans.

These are but a few of the initiatives that are on our agenda, as you will here there are several more projects such as, preparing good manufacturing practices for dietary supplements; trying to improve the food labeling with respect to allergens; doubling our food inspections at the ports of entry; and we are stepping up our enforcement against potentially harmful nutritional supplements. We even test typical home-cooked meals for residues of pesticides and other contaminants.

Medical Errors/Patient Safety

A third critical step of our agency is to reduce adverse health events involving the products we regulate. Health problems associated with adverse events are far too common, carry a staggering economic tab and a large number of them are preventable. The statistics on the prevalence of avoidable health complications that often involve the use of FDA-regulated products presents a huge challenge for our agency and for all of us.

One type of an often preventable adverse events results from foodborne disease. According to a 1999 survey by the Centers for Disease Control and Prevention,CDC, foodborne diseases cause annually 76 million cases of illness, 325,000 hospitalizations, 5,000 deaths, and an economic damage of up to $23 billion. In addition, inadvertently consumed food allergens result in thousands of avoidable emergency room visits.

Another often preventable adverse event is the misuse of pharmaceuticals which is associated with thousands of deaths and about 3 million hospital admissions a year. It is estimated that our pharmacists will fill 3.1 billion prescriptions by the end of this year, 60 percent more than 10 years ago. Manufacturers worldwide are increasingly presenting their new pharmaceuticals for FDA's review and approval: 60 percent of the world's drugs are introduced first in the United States. In 2000, the economic cost of drug-associated errors alone was estimated to reach over $75 billion a year. Finding creative ways to prevent even a fraction of the preventable medical errors, will improve the lives of hundreds of thousands of Americans, and greatly reduce the burden on our health care systems.

The FDA's MedWatch program is a system of voluntary reporting of adverse events associated with the use of agency-approved products. The agency's MedWatch program receives about 250,000 voluntary adverse event and medical product problem reports each year, mostly from health care professionals and consumers. Our Vaccine Adverse Event Reporting System, VAERS is shared with CDC and includes participation by large health plans. The Centers for Education and Research on Therapeutics, CERTs, which was authorized by the FDA Modernization Act and is administered through grants from AHRQ, is helping collect information on safe and effective use of FDA-approved medications. And we see the most promising emergence of increasingly sophisticated electronic databases that make possible public-private collaboration in learning more about the ways to improve the safety of medical treatments. Another bright spot is MedSun, FDA's pilot program for devices that requires rapid adverse event reporting on medical devices by a group of hospitals and nursing homes. The system advances the public's health by giving FDA quicker and more detailed information, without identifying involved individuals, on potential problems with health care products in actual medical practice. FDA's VAERS received more than 14,000 reports of adverse reactions in fiscal year 2002, most of which were volunteered by health care providers, patients and their parents. I am looking forward to the debut in June of the newest adverse event reporting system in FDA, the Center for Food Safety and Applied Nutrition Adverse Events Reporting System, CAERS will track voluntary submitted food and cosmetic adverse reports and incorporates some of the latest technology.

But that's not all FDA is doing. Recently, FDA made some additional major patient safety announcements. These included a proposed rule to require a universal barcoding system for prescription medications, to support the development of better systems to support health professionals. The proposed barcode rule would apply to all prescription drug products, including biological products and vaccines, except for physician samples, as well as over-the-counter drugs that are commonly used in hospitals. The proposed rule, if finalized, could reduce by half or more the large number of medication errors that occur at the dispensing and administration stage, by helping to make sure that the right patient gets the right drug at the right time.

A second proposed action the FDA recently announced—revamping of our manufacturer reporting requirements for adverse events—aims to enhance the agency's ability to effectively monitor and improve the safe use of medications including drugs and biologics. Among other things, the proposed rule would improve the quality and usefulness of safety reports submitted to the agency, by giving us more detailed information on serious actual and potential adverse events, especially those involving new products where toxicities are not yet thoroughly understood. It also uses standards that we have developed with regulatory agencies around the world to develop, so that manufacturers can submit one accurate and complete report to agencies rather than many. The proposal will require the submission of all suspected serious reactions for blood and blood products, not just deaths. These provisions would provide FDA with more useful, timely, and extensive information to support quicker, more effective actions by the agency to prevent adverse events.

FDA is also working to reduce adverse events associated with dietary supplements. With new evidence in the medical literature and in adverse event reports there are reasons for the heightened concern that dietary supplements containing ephedra, consequently FDA and HHS announced a series of steps recently to protect Americans from the potentially serious risks of these dietary supplements. The law governing dietary supplement requires us to prove, scientifically and legally, that a supplement presents an unreasonable risk in order for us to take regulatory action. Thus, we are seeking rapid public comment on the new evidence on health risks associated with ephedra to establish an up-to-date record as quickly as possible, to support restrictions on ephedra-containing products and the need for a strong new warning label on any ephedra products that continue to be marketed. We are also executing a series of actions against ephedra products making unsubstantiated claims, for example about sports performance enhancement, and against manufacturers that are marketing street drugs not dietary supplements.

To help consumers continue to get unadulterated dietary supplements, we also proposed a major new regulation to require good manufacturing processes in their production, packing, and holding. The proposed rule would, for the first time, establish standards to help ensure that dietary supplements and dietary ingredients are produced without contaminants or impurities.

I intend to expand the use of new information technology, IT, to improve our understanding of what causes preventable adverse events. In medical care, it is conceivable to develop of an electronic network that would provide automatic updates on adverse events and the circumstances that may have contributed to their occurrence. Such information network could also enable the FDA to disseminate automatically updated, relevant information on medical labels and warnings, and thereby help prevent the adverse events from happening again. Our agency is already conducting pilot IT programs in our centers for medical devices, drugs, and biologics.

Potential health benefits can result from an effective use of today's IT. For example, IT can help professionals monitor the patient's progress and deliver a health care that "gets it right." Many of the new, complex treatments have an inherently higher potential for toxicity, and their use requires careful monitoring for liver, kidney and other toxicities, as well as for interactions with the patient's conditions and other medical treatments. The technology can also aid in the sophisticated monitoring and support required by many seriously ill patients who have undergone complex and sometimes lifesaving surgical procedures. Used comprehensively IT would form the backbone of a National Health Information Infrastructure, a system capable of rapidly and securely transmitting significant health-related data to institutions and public health professionals who need them to ensure better care for patients. My vision is for the FDA to support and use these new tools of health information technology and their incorporation in this system, and pen new opportunities for advancing our mission of promoting the public health. The Administration's Consolidated Health Information E-Government initiative, to which FDA is contributing, is working to establish broad health data information standards that will apply to all agencies.

These and other advancements are part of a vision of what can be accomplished if all of us in government, the health professions, academia and industry continue to work toward better health information systems—and more generally, toward a health care system that helps patients and health professionals make better decisions supported by safer and more effective medical treatments.

We have a major opportunity to help people improve their health by providing them with the up-to-date information they need to choose a healthy way to live. As the Secretary pointed out this is a human tragedy and a shocking result of a failure to realize many of the potential benefits of modern medical treatments. In my new post, I look forward to supporting FDA's efforts to fulfill its important role in this process, and to help secure the benefits of a robust 21st century health care system.

Consumer Information

A fourth step to address FDA priorities is to help consumers get reliable, accurate, and relevant information about the FDA-regulated products. For all that the new medical technologies in the review pipeline can accomplish, they cannot match the public health benefits of sound lifestyle and dietary choices that individuals can make themselves. It is also vitally important for consumers to have accurate and truthful information about the risks and benefits of the medical products they use. Americans increasingly want to learn more about what they can do personally to maintain or improve their health. That's why I am placing such a high priority on clearly communicating that information—not only to consumers, but to health care providers and others who can help ensure that consumers make important decisions about their own health on the basis of reliable information.

To mention a couple of familiar examples, our agency is introducing more and better information about the foods and dietary supplements to help American consumers prevent diseases and improve their health by making sound dietary decisions. One effort is nutrition labeling, which encourages shoppers to select foods low in cholesterol and saturated fats, and high in fiber. We will soon be adding a requirement to include "transfat" on the nutrition label.

But consumers today expect us to do still more, and we must not disappoint them. We must disseminate up-to-date and reliable scientific information on the health effects of foods and nutritional supplements; and we must make sure that the ads and claims for medical products, foods, and dietary supplements are truthful and not misleading. Moreover, we must make use of all means to get this information to consumers in a way that would most benefit their health.

There is no example more persuasive of the need for innovative approaches than the national epidemic of obesity. This is a very serious, and growing, public health problem. According to a CDC survey, in 1985 fewer than 14 percent of Americans were overweight.

Today, more than a third of our adult population is obese, 64 percent of U.S. adults are obese or overweight, and 15 percent of 12–19 year-olds are overweight. The health consequences include greater incidence of diabetes, stroke, coronary artery disease, cardiovascular disease, and high blood pressure—and that's not the complete list. The economic costs of diseases linked with excess weight run into hundreds of billions of dollars each year.

Although the FDA has approved drugs for curbing appetite and breaking down dietary fat, their use usually does not result in a weight loss greater than 10 percent. There is no better remedy for excessive weight than healthy lifestyle choices—and to make these choices, consumers need better information on how their diet affects their health. Our agency has been helping to provide such information through educational articles, guidelines and press releases.

But FDA cannot achieve the goal of a well-informed public through labeling requirements and agency educational campaigns alone. We also need to find better ways to encourage food producers to compete on the basis of scientifically sound nutritional claims. As a recent study by the Federal Trade Commission noted, ads with scientifically-based health claims can have substantial positive effects on the choices of consumers. Here is one area where we may be able to get more useful nutritional information to consumers.

By putting credible, science-based information in the hands of consumers, we hope to foster competition based on the real nutritional value of foods rather than on portion size or spurious and unreliable claims. Such labeling can help empower consumers to make smart, healthy choices about the foods that they buy and consume.

Our consumer health information initiative includes three related actions. First, we will issue guidance on qualified health claims for conventional foods and dietary supplements. Any such claims must be pre-approved by FDA and meet the "weight of the scientific evidence" standard, including support by a credible body of scientific evidence; Second we will strengthen enforcement of dietary supplement rules. Today, FDA is emphasizing its commitment to carrying out the intent of Congress in the Dietary Supplement Health and Education Act of 1994 by outlining its enforcement strategy against false or misleading claims about dietary supplements. As an example of its commitment to strong enforcement, FDA has seized dietary supplements making unapproved drug claims. Third, we have established a Task Force on Consumer Health Information for Better Nutrition. This task force will develop a framework to help consumers obtain accurate, up-to-date, and science-based information about conventional food and dietary supplements. This includes the development of additional scientific guidance on how the "weight of the evidence" standard will be applied, as well as the development of regulations. Our mission at FDA is to improve health outcomes for the nation, and some of the best opportunities for improving health involve informed choices by consumers. Through the Better Health

Better Information initiative, we are committed to improving opportunities for consumers to get scientifically accurate information about the health consequences of the foods they consume, and to enhancing our enforcement efforts against those who would make false or misleading claims for their products.

Counterterrorism

A fifth step in meeting our challenges is to address the critical additional responsibilities—the nation's front lines against terrorism. Helping protect our homeland is a privilege and our paramount public health job, and we are doing all we can to deserve the trust placed in our agency. Our product centers responsible for pharmaceutical products are working to adapt their approval processes to the unique challenges of developing safer and more effective treatments for anthrax, smallpox, plague and other potential agents of bioterrorism. Our center for medical devices is supporting the development of methods for detecting biological agents with bioterrorism potential, and for radiological decontamination. These new tools are needed now, and we are doing our best to help bring them to the nation's defense as quickly as possible.

A new initiative recently announced by the President Bush is Project BioShield—a comprehensive effort to develop and make available modern, effective countermeasures against biological and other dangerous agents. This major cooperative effort will be a joint activity of the new Department of Homeland Security and the Department of Health and Human Services. The BioShield program which Congress is currently considering will ensure resources to develop next-generation countermeasures for smallpox, anthrax, and botulinum toxin; expand research and development at NIH so that it in order to speed research and development on medical countermeasures based on the most promising recent scientific discoveries and make promising treatments available quickly for emergencies. The BioShield program would provide FDA with the ability to make new and promising treatments under development available quickly in emergency situations—potentially saving many more lives than treatments otherwise available today.

The President believes, by bringing researchers, medical experts, and the biomedical industry together in a new and focused way, our Nation can achieve the same kind of treatment breakthroughs for bio-terrorism and other terrorism threats that have been achieved to the threat of heart disease, cancer, and many other serious illnesses.

We have no responsibility more important and challenging than to protect the safety and security of the United States food supply. This is especially true as 80 percent of food products are within the FDA's purview. We are also involved in ensuring the safety of many new types of food. We all know the problem of food safety did not originate in September of last year. During the last decade, rising incidence of food contamination with Listeria, Salmonella and other pathogens—combined with our more diverse and aging population, greater preference for prepared foods, and rapidly growing food imports—have sharply increased foodborne outbreaks that produced the CDC statistics I mentioned.

This past year the CDC reported a 21-percent decline in illnesses from four more common serious foodborne pathogens, and a food safety survey conducted in 2001 reported substantial improvement in the way our consumers handle food. But the terrorist attacks last year highlighted new potential risks of deliberate food contamination. To counter this unprecedented menace requires new thinking on how to better safeguard our food.

Much work toward this goal has already been done. In the fall of last year, for example, our agency initiated a scientific assessment of the vulnerability of various categories of food to intentional contamination. The appraisal utilized an analytical framework called operational risk management that considers both the severity of the public health and economic impact of a potential bioterrorist attack on our food supply, and the likelihood of such an event taking place. The FDA has developed two guidance documents—one each for domestic food producers and for food importers—on how to protect their products against intentional contamination. And, we are developing additional guidance directed at the retail and cosmetic sectors.

One special emphasis is on the security of our food imports, the volume of which is increasing by as much as 21 percent a year. In particular, the FDA is taking part in two multi-agency efforts to give our bioterrorism counter-measures greater scientific depth and geographic distribution. Thanks to the leadership of the Undersecretary of the Food Safety and Inspection Service, (FSIS), we have joined with FSIS and several other Federal agencies in laying the groundwork for PrepNet, a network focused on the prevention of—and response to—the introduction of microbial, chemical, radiological or physical contaminants into the food supply. And we are developing plans for cooperative work with and expansion of CDC's cooperative Labora-

tory Response Network that will upgrade our ability to quickly recognize and identify a terrorist attack on food.

Our efforts to improve food security have received strong support from the President, the Secretary of Health and Human Services, and you—the Congress. Thanks to a supplemental appropriation of $151 million received in fiscal year 2002, we have been able to hire several hundred new employees whose job will be to keep watch on imports and whatever other avenues our enemies might try to use to contaminate our food or tamper with other regulated products. But it is important to keep in mind that reducing risks to food security requires more than hiring inspectors. Even with the great expansion of FDA's presence in the nation's ports of entry, we will be able to inspect only a fraction of the 5.6 million food shipments that will be imported this year.

We need to find innovative ways to make our foods more secure without adding unnecessary costs. Thus additional efforts are in the works. One is the implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which gives the FDA greater control over food in general, and imported food in particular. Secondly, several weeks ago we announced a set of new food security measures as part of Operation Liberty Shield. Operation Liberty Shield is a comprehensive, multi-agency national plan designed to increase protections for America's citizens and infrastructure while maintaining the free flow of goods and people across our border with minimal disruption to our economy and way of life.

The Bioterrorism Act contains a number of food provisions which require new regulations. We have now published four proposed regulations, three of which are mandated to be in effect by December 12, 2003. This project is on the fast track, and I am committed to issuing the final rules by their statutory deadline. The registration of will require all facilities that manufacture, process, pack or hold food for consumption in the United States to register with the FDA by mid-December, 2003. A second regulation will require importers to provide the FDA with a prior notice of food shipments that includes information about the shipment's contents and origin, as well as the anticipated port of entry. A third regulation will obligate food businesses to maintain records to enable us to determine where the food came from and who was its subsequent recipient, so that we can quickly trace any food contamination back to the source. The fourth regulation authorizes the FDA to order the detention of food on the basis of credible evidence or information that it poses a serious health threat to humans or animals.

Liberty Shield, our newest undertaking, focuses on published common-sense food guidance documents on food security relevant to just about all firms involved in food production, ranging from the smallest mom-and-pop operations and county fairs to the largest food producers. The guidances cover all major sectors of food production, distribution, and use.

Another focus of Operation Liberty Shield, is increased food inspections and sampling for important agents of terrorism. We have recently invested over $1 million in emergency funds to purchase test kits that enable us to sample for these agents, and we are starting to use these kits more widely in our inspections and testing of both domestically produced and imported foods.

We'll be undertaking further efforts to work with the food industry as we carry out investigations and import audits, and as we implement new procedures, to make sure the measures lead to the greatest benefits for food security without imposing unnecessary costs or regulatory burdens on food production, processing, and distribution. And we want to make sure firms remain aware of potential terrorist activities, especially as they relate to raw material shipments, inventory quarantine procedures, sourcing of foreign products or ingredients, and vulnerable operations

Over the coming years, I believe the best solution will be the adoption of a risk-based import surveillance system to replace our current import program, which is fully linked with U.S. Customs entry processes—processes that have historically been designed to address revenue and trade issues, not public health issues. We're moving in the direction of a modern, risk-based system for food imports already. This includes shifting toward a "life cycle" approach. I am confident of our agency's ability to rise to the many new challenges we face and I look forward to working with you. Now for the budget request

Fiscal Year 2004 Budget Request

As I have mentioned, pivotal to the continued success of the FDA and the success of the President's efforts to promote health care quality is the FDA budget Our fiscal year 2004 President's budget request totals $1.7 billion, including $1.4 billion in budget authority and $307 million in user fees. Budget authority increases above the fiscal year 2003 Appropriation total $82.6 million and savings related to the President's initiatives total $58.2 million. The agency's reductions include transfer-

ring funding to the new Department of Homeland Security, management savings due to de-layering, and information technology consolidations. The user fee increases total $37 million. The full time employee total equals 10,753, which includes the adjustment for management savings.

We believe our budget request will allow FDA to fund ongoing operations at the current level and also support more than 1,000 recently hired investigators and analytical staff to fight counterrorism. In the near future, FDA will be challenged to resolve complex issues connected with emerging technological and demographic developments that include the human genome project, breakthrough device technology, and biotechnology medicines and development. Our specific budget initiatives as compared with our fiscal year 2003 President's request parallels our top priorities.

The President's 2004 Budget was developed within a framework that set a proposed total for discretionary spending in 2004, and each agency and program request reflects the Administration's relative priority for that operation, activity or Program. Thus, the fiscal year 2004 budget has not changed based on the program or agency levels included in the 2003 Omnibus bill the Congress approved in mid-February. We recognize that you may believe there is a need to reorder and adjust some of these priorities and the Administration intends to work with you to remain within the 2004 top line amount.

Cost of Living $31.4 million

Essential to FDA's success is its dedicated professional staff. FDA is a people-intensive Agency where payroll accounts for over 60 percent of the budget. Forty-five percent of that workforce is dedicated to "front line" efforts such as foreign and domestic inspections and coordination with States and cooperative education programs. The budget request includes $23.283 million in inflationary cost-of-living adjustments which will be used to support the level of existing programs and also provide a minimum level of support to the hundreds of investigators and analytical staff hired in fiscal year 2002 for Counterterrorism activities. And, the request includes an additional $8.108 million that will be used, in part, to defray other pay costs, making up the difference between a 3.1 percent versus a 4.1 percent pay increase.

As I have said, the importance and complexity of the FDA's work will only increase in the years to come. Thus the continued success of our mission depends on the experienced and highly dedicated professionals who can make our regulatory decisions balanced and fair keeping us on the cutting edge of the technology and sciences used by industry. Making sure FDA's working environment encourages creativity, efficiency and performance is one of my goals.

Secretarial Initiative: Protecting Our Homeland: Food Safety—Counterterrorism $20.5 million

FDA has limited capacity to monitor or control the flow of imported foods, inspect domestic manufacturers, and detect foodborne pathogens before they cause human illness. When these limitations are combined with the possibility of deliberate attempts to contaminate the food supply at any point along the food production, processing and distribution chain, the risks are greatly increased. We believe that a coordinated approach with state, Federal and local partners, offers a better means of identifying and containing outbreaks associated with deliberate attempts to contaminate the food supply.

One key food provision of the Bioterrorism Act is the requirement for registration of domestic and foreign food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the agency by December 12, 2003. FDA also plans to have its registration system operational by October 12, 2003, to accept early registrations.

Improving the FDA's food safety inspection, detection and monitoring capabilities is and has been a top priority of the Department and the agency before the events of September 11. This FDA effort is the latest in a series of measures to build stronger safeguards for the American people.

We believe these measures will bolster our ability to regulate effectively the more than 400,000 domestic and foreign facilities that deal with food within our country. Our ability to efficiently and effectively help protect the nation's food supply is a critical part in our agency's counterterrorism mission. Thanks to the leadership of Senators Gregg and Kennedy, and Representatives Tauzin and Dingell, the Bioterrorism Act gives FDA this important new authority.

FDA will also provide grants to states for inspections under section 311 of the Bioterrorism Act, conduct direct Federal food inspections, and improve Center and Field laboratory preparedness. By increasing the number of state contracts, grants and partnerships, we believe it will ensure application of appropriate preventative

controls to ensure a safe, wholesome, and nutritious food supply. We expect the initial grants to be used by the states to build their infrastructure so that they may become part of the Laboratory Response Network. With better assessment capabilities of the risks to FDA regulated products we will focus efforts by directing the grants toward risk based inspectional activities or additional laboratory capability.

The infrastructure needed to support the Laboratory Response Network, LRN for counterterrorism coordinated by the CDC, provide integrated laboratory solutions and disseminated testing capacity to support public health preparedness and response to an act of counterrorism involving the food supply, FDA will develop scientific practices, expand Federal, State and local involvement in our eLEXNET system by having 79 laboratories around the country participate in a common shared microbial agent electronic data system, while assuring coordination with other members of the Public health Information Network. The total effect is the creation of a safety net that significantly reduces the probability that terrorists will ever achieve their aims, and minimizes the impact of these threats if they do occur.

Secretarial Initiative: Realizing the Possibilities of 21st Century Health Care: Patient Safety $4 million

FDA's public health and safety role requires a rigorous and effective postmarket surveillance activity. When FDA approves drugs and other medical products such as devices, it has completed a thorough review to determine that these products are safe when they are marketed. That is not always the end of the story. New safety findings may emerge after approval, when a wider patient population uses products. In some cases, products may not be used safely to prevent harm. It is important for FDA to continually monitor these products and track trends associated with them. A critical task of the agency is to reduce adverse health events, a large number of which are preventable. Medical errors are estimated to account for 40,000 to 100,000 deaths per year in hospitals alone.

The requested increase of $4 million, coupled with the $3 million from our Generics Drug request will allow FDA to expand the use of new information technology to improve our understanding of what causes preventable adverse events. FDA will continue to conduct pilot IT programs for medical devices, drugs, generic drugs and biologics as well as continue the implementation of Phase III to include drug products into the Medical Device Surveillance Network, MedSun. FDA's new safety initiative, using modern health information systems, will provide faster and more complete information on safety problems associated with drugs and devices so adverse events involving these products can be avoided. Additionally, FDA will place greater emphasis on preventing adverse events involving generic drugs.

Generic Drugs Program $13 million

According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generic drugs. A generic drug is identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are therapeutically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.

Brand-name drug innovation requires great investment of scientific effort and other resources, with an uncertain return. We all therefore recognize that innovators must be able to receive adequate compensation through our patent system. Otherwise, pharmaceutical research and the development of better medical treatments could come to a halt.

But it is also clear that the high prices of many innovative drugs in the United States, where they are not restricted by government controls, are sustaining pharmaceutical research and development worldwide. This is good for pharmaceutical innovation, but it also creates a serious challenge for many of our patients, who are having difficulty paying the high and rising costs of up-to-date drug treatment.

This is where the generic drug industry plays an essential role in promoting the health of Americans. Generic drug manufacturers produce medications that are just as safe and effective as their brand counterparts, and part of the FDA's mission is to make sure that's the case. Yet the prices of generics are much lower: a generic version of a $72 average brand-name prescription costs about $17. And thanks to more brand-name medications coming off patent—over 200 of them in the next few years—as well as to the ever-improving scientific knowledge and public awareness about the benefits of generic drugs, the health and economic benefits of using generic drugs are constantly growing.

Encouraging rapid and fair access to generic medications after the expiration of appropriate patent protection is, therefore, one of my major priorities as FDA Com-

missioner. Americans need more generic drugs more than ever, and the FDA has to do its part to make these products available. There are many steps involved in achieving this goal, and I want to walk through some of them

One part of achieving this goal—reducing the net review time—is largely under the control of the FDA. It's a function of the efficiency of our review process and our available resources. Our Office of Generic Drugs (OGD), has been making progress in this area. Despite the growth in the submissions of original abbreviated new drug applications (ANDAs) from 309 in 1999 to 361 in 2002, our generics program during the same time increased the proportion of applications reviewed within 180 days from about 28 percent to 80 percent. The average time required for a first review of an ANDA is down to 100 days, from 135–140 days in the late 1990s.

These substantial improvements were made possible by rising efficiency in the generics office, as well as by increased resources. The appropriations for this office increased by $1.4 million in 2001, by $2.5 million in 2002, and another $5.3 million in 2003. I thank you for your continued support of this vital program. We can and will do more to improve the efficiency of our reviews, and acting quickly on generic drug applications is well worth even greater FDA resources. Moreover, we hope and expect that the number of generic applications will continue to grow above this year's record level of almost 400 ANDAs. We will use the $13 million requested in 2004 to improve our reviews and to handle the growing workload. It will increase the size of the generics programs by about 30 percent.

With this funding request, we will be able to hire about 40 additional staff in generic drugs, and add to OGD an additional division for the review of chemistry. This expansion should help reduce the average review time by at least 2 months, move up the proportion of 180-day reviews still closer to the 100 percent goal, and further reduce the waiting time in the ANDA queue. What we need is actual improvement in generic drug availability. And to get more generics in the pharmacies and to our patients' bedsides, we have to meet two additional requirements.

First, the products we review must be safe and effective—meaning, they must demonstrate therapeutic equivalence to the brand drug, and they must be appropriately labeled and safely manufactured. And second, there must be the minimum of legal challenges to the marketing of generic drugs. And in considering both of these very important factors, we see some positive developments—as well as some concerns.

On the positive side, the number of full and tentative generic applications approved has gone up significantly, from 242 in 1999 to 384 last year—an all-time record. On the other hand, median time to the issuance of an approval or "tentative approval" letter—which used to be longer than 2 years—is yet to drop below 18 months. That means, even as we are making large strides in reducing our review time, there is still substantial room for improvement in total time to approval. And although many generic applications have been approved within 1 year, this timeframe is still the exception rather than the rule. Moreover, even after the FDA issued a tentative approval, some potentially important generic drugs have remained unavailable because of legal challenges.

The reason that total time to approval or tentative approval is not declining as much as we might hope is that, very often, multiple review cycles are required. Unfortunately, a large share of the initial generic applications are not up to the FDA's requirements. And this critical obstacle to increasing generic drug availability cannot be removed by the FDA alone

The second main obstacle to effective communications has been FDA's internal policies that discouraged early consultations between OGD reviewers and sponsors of ANDAs. In part, these policies were necessary because the generic drugs staff has been—and is—overwhelmed with review work, and could not take on additional tasks.

We are considering modifications to our policies on communications involving generic applications during the review process. I have therefore asked the Director of our Center for Drug Evaluation and Research (CDER), and the Director of the Office of Generic Drugs to lead an effort to identify steps, such as improving the clarity, consistency, and timeliness of our guidance and communications for generic drug applicants, to help improve the level of understanding and quality of applications by generic manufacturers.

A third key factor affecting the availability of safe and effective generic drugs is manufacturing processes. To ensure safety and prevent adulteration, generic manufacturers must comply with Good Manufacturing Practices. Pharmaceutical GMPs, and the system that enforces them, still get the job done. But they have not been updated in many years, and it's time for reform to make sure that we have a GMP system that achieves its critical goals as efficiently as possible.

I will now turn to another critical factor affecting generic drug availability: uncertainties in the legal landscape that generic manufacturers face. Recently, as you well know, there has been tremendous interest in whether reforms are needed in FDA's regulations to implement the Hatch-Waxman law that governs generic drug competition, or whether there need to be reforms in the law itself.

While hundreds of generic drugs enter the market each year without substantial legal obstacles, some aspects of FDA's current interpretation of the law have been associated with disruptions, delays, uncertainty, and added costs for some generic manufacturers who are trying to compete fairly against some of the most important brand-name drugs in the country. On occasion, generic manufacturers who have geared up to compete following the expiration of what they thought were the relevant brand-name patents, only to learn that they had new patents to contend with. This practice lead to the repeated use of the so-called "30-month stays" of full approval of ANDAs and 505(b)(2) applications.

To address this problem, the FDA proposed a new regulation last fall. The proposed rule would allow only a single 30-month stay per generic drug application. The proposed rule would clarify that certain types of patents are not allowed to be submitted for listing in the Orange Book, while others for method of use, formulation process, product by process, and different forms of the pending or approved drug substance must be submitted for listing. Further, the proposal would substantially strengthen the signed declaration accompanying the patent submission. These measures should reduce the submission of patents for Orange Book listing that do not represent true innovation.

Secretarial Initiative: Accelerating the Availability of Lower Cost Drugs—Improving Health Sciences: Over-the-Counter Drugs (OTC) $1 million

OTC drugs play an increasingly vital role in America's health care system, and provide an effective means to significantly reduce consumer prescription costs for specified ailments. The trend to self-medication has increased significantly in recent years as health care costs have risen and consumers want to be empowered to treat minor ailments with safe and effective OTC drug products.

The increase will support the hiring and training of seven FTE to improve the OTC drug review process so that FDA is better equipped to provide the consumer faster access to OTC drug products without compromising safety issues; expedite the review of Rx-to-OTC switches; and, develop and work toward finalizing standards—monographs—for analgesic, antiseptic, laxative, and sunscreen drug products for OTC use. All of these efforts help produce significant consumer benefits such as significantly reducing and/or eliminating all unsafe and ineffective products from the OTC market; providing greater and broader access to OTC drug products; reducing some health care costs; and increasing competition.

Best Pharmaceuticals for Children Act $5 million

Pediatric provisions included in the FDA Modernization Act of 1997 have had a profound impact on the study of drugs used for children. On January 4, 2002, Congress enacted the Best Pharmaceuticals for Children Act (BPCA), to continue providing incentives for the effective development and dissemination of information on how to properly use therapies in children.

Currently there is still not enough information regarding the pediatric use of about 75 percent of prescription medicines. Prior to implementation of the pediatric provision, 80 percent of medications had not been tested on children, forcing pediatricians to guess at dosage for children, subjecting our children to dangerous health risk in terms of under dosing or over dosing. This is a particularly serious and dangerous situation for the newborn and those infants born prematurely. We know the bodily functions of infants are different than adults and in particular their response to various therapies. We believe this provision will continue to result in pediatric patients being given medicines that have been properly evaluated for their use in the intended populations.

With the increase, FDA seeks to expand availability of drugs for children. We will strengthen our coordination with NIH on ensuring the safety and efficiency of pediatric drugs. FDA and the NIH will develop, prioritize, and publish an annual list of approved drugs for which there is a referral, an approved or pending new drug application, or no patent or market exclusivity protection and for when additional pediatric safety and effectiveness studies are needed, establish a research fund for the study of drugs that no longer have exclusivity or patent protection and specifies the process for obtaining contracts; provide a public summary of all studies. In fiscal year 2003 NIH received $25 million to expand the availability of drugs for children, in fiscal year 2004 NIH is requesting an additional $25 million for a total of $50 million was to support this effort.

FDA will hire new staff for our Center for Drug Evaluation and Research, CDER to continue to define, develop, issue, and track written requests for pediatric studies; publish the final study reports on the docket; review submitted results from these pediatric studies within 6 months; oversee ethical issues related to studies; and disseminate appropriate information to the public. The increase will also support the hiring of 4 FTE in the Office of Pediatric Therapeutics, under the heading of Other Activities, to address all activities related to the increasing number of new pediatric studies submitted by the pharmaceutical sponsors.

Secretarial Initiative: Improving Departmental Management

FDA is also supporting various administration and department initiatives associated with the President's Management Agenda by consolidating human and IT resources to achieve greater efficiencies and economies of scale; consolidating the biologic therapeutic review function into the similar drug review function to achieve greater consistency and less duplication of effort, conducting outsourcing studies and improving management to achieve cost savings and maximum efficiencies; organizational de-layering for faster decision-making and better communications; and, implementing a new financial management system to provide agency managers with timely and consistent financial information.

FDA plans a major consolidation of its Headquarters Offices in the Washington D.C. metro area going from 16 locations to two—White Oak and College Park, Maryland. These locations were selected to create greater economies of scale and scope with the co-locating, standardizing and modernizing document handling; sharing facilities such as libraries and conference areas; reducing redundancies in a wide range of administrative management tasks; allowing the conversion to a single computer network; and significantly reducing management layers. College Park has been completed.

Center for Drug Evalutation and Research Move $6 million

FDA headquarters currently occupies approximately 40 buildings in 16 locations. A long term goal has been for these facilities to be consolidated into two locations which will result in considerable annual operating savings. Receipt of the request will complete the second phase of the CDER relocation. This portion of the second phase will consolidate the offices and laboratories of CDER into one office and laboratory complex, enhancing communication, primarily by supporting cabling and relocation services.

Arkansas Regional Lab $3.5 million

FDA is also strengthening its analytical capabilities in the field by completing Phase III of the Arkansas Regional Laboratory multi-purpose facility to support the increased need for domestic and import inspections efforts.

FDA's field laboratories provide critical laboratory and analytical support to domestic and import inspection efforts and are a key element to the FDA science base. These laboratories provide a cost-effective critical mass of scientific expertise in the fields of chemistry, microbiology, pesticide chemistry, animal drug research, and total diet research. ARL, located in the middle of the United States, will provide critical laboratory analysis for FDA-regulated products in a seventeen-state radius.

Completion of Phase III of the ARL will enable FDA to fully utilize Building 50 and effectively collaborate with the National Center for Toxicological Research on scientific issues critical to the Agency and the American public. One of the issues addresses FDA's preparedness for counterterrorism events. The Jefferson Laboratories are developing DNA-based or mass spectrometry based technologies to permit the analyses of products for chemical and microbiological hazards. These methods will assist public health officials in identifying the type of hazard and its appropriate counter-measure.

Without these funds, Phase III will not be completed in a timely manner and that delay may adversely impact FDA efforts to finalize development of methods, which could be used for chemical and microbiological hazards.

Unified Financial Management System $2.3 million

FDA's management needs timely, reliable, and current information. The DHHS Unified Financial Management System, UFMS, is designed to provide financial information in a manner that will enable FDA to maintain its clean audit opinion and meet all other financial information management requirements.

FDA is performing various preparatory activities such as consolidating fifteen agency location codes to one; standardizing computer financial systems by implementing web-based versions; and, preparing its financial community for changes. Additional funding in fiscal year 2004 will enable the FDA to implement its portion of UFMS titled, Financial Enterprise Solution by beginning to design and test the

General Ledger with payroll interface, which will account for over 60 percent of FDA's transactions; and purchase software licenses, hardware, training and program support and meet increased contractor costs for site implementation.

Rent Redistribution $10 million

FDA is working with GSA to obtain space around the country to accommodate the more than 800 counterterrorism personnel hired with fiscal year 2002 Emergency Supplemental Appropriation. FDA anticipates redistributing some funds in fiscal year 2003 for GSA rent costs, and we are working to determine the exact amount of this redistribution. FDA expects its GSA rent costs to increase by at least $10 million in fiscal year 2004. In an effort to achieve additional management efficiencies, FDA intends to redirect funds from the programs, including field activities, to cover cost increases. Similar redistribution of increased GSA rent costs may all take place in fiscal year 2003.

Reorganizations and Improving Management

To meet my priorities of a strong and effective organization, risk reduction, counterterrorism and food security, and reducing medical errors and consumer communications, FDA has reorganized and several functions within the Office of the Commissioner. These include the Office of the Senior Associate Commissioner, the Office of Crisis Management, the Office of Legislation and the Office of Combination Products. In addition, the therapeutic biologics review function is being transferred from CBER to CDER to consolidate the similar drug review functions. Organizational de-layering to achieve a flat, streamlined Agency where decision-making and better communications exists is being aggressively pursued. FDA is also consolidating its administrative functions into a Shared Services Organization, SSO. The SSO concept will allow FDA to provide administrative support functions to Agency components to meet critical mission needs in the most efficient and effective manner possible. Similarly, FDA actively participated in leadership with the Department in the 40 to 4 Human Resource, (HR) consolidation effort. FDA's HR Director chaired the Department's workgroup of Operating Division representatives to design the new 40 to 4 HR consolidation initiative. FDA also conducted the pilot of a web-based application process called "quickhire" which is the system to be used supporting operations at the four HR centers. In preparation for the 40 to 4 consolidation, FDA consolidated its six personnel offices into one in 2002.

As we prepare to transition FDA's HR staff to the Department's Rockville Service Center, scheduled to begin operation on October, 1, 2003, I will continue to support the Department's consolidation initiative. These efforts will place the Agency in a position to more effectively and efficiently meet the challenges of providing better protection to consumers and promoting better health.

Management Savings $25.7 million

Management savings in fiscal year 2004 will contribute to an environment in which the FDA functions effectively as a single agency that consistently supports top-quality work by all of its employees.

The challenges facing FDA cannot be confronted adequately without adequate resources in the right places. By rightsizing the Agency is thinking critically and carefully about how it uses its resources to improve the public health. Innovation and change is the norm in the American health care system, and programs must be designed with the future in mind.

To accomplish this, FDA is conducting sourcing studies and improving management to achieve cost savings and maximum efficiencies for a fiscal year 2004 savings of $25.698 million and 199 FTE.

IT Consolidation $29.6 million

Information technology infrastructure functions are also being consolidated. This consolidation effort will reduce IT infrastructure and development expenditures in fiscal year 2004 by $29.587 million. Similar systems will be combined, IT processes reviewed and there will be reduced efforts on lower priority projects. Standardization of management processes will be fostered to increase the effectiveness of IT even as overall costs are reduced.

User Fees—Current Law User Fees $31.7 million

The budget request includes $249.825 million in PDUFA III user fees for the drug and biological product review process, an increase of $26.925 million over fiscal year 2003. This consists of pay and inflationary increases and new initiatives included in the PDUFA III legislation.

In addition, the request includes $29.190 million for MDUFMA to significantly improve the medical device review process. This is a $4.065 million increase over fiscal

year 2003. Our Medical Device and Radiological Health program has re-engineered itself over the last decade to accomplish more and has changed its strategic direction by consciously shifting its focus to high-risk, high-impact products to optimize the effect on public health. Other innovations brought by the FDA Modernization Act have streamlined the processing of premarket notifications (510(k)s) by using accredited third parties. The results were improvements in the review times and review processes. MDUFMA builds on these successes by providing medical device user fees beginning with fiscal year 2003 submissions, authorizing the use of accredited third parties to conduct quality systems/GMP inspections under very rigorous conditions, providing for effective FDA oversight of reprocessed single-use devices, improving the focus on devices intended for pediatric populations, improving the coordination of reviews that involve combination products, and more.

MDUFMA commits FDA to a comprehensive set of challenging performance goals that will lead to substantial improvements in the timeliness of device reviews. MDUFMA user fees, and the additional appropriations you provide for this important program, will ensure FDA's ability to bring new medical technologies to health care professionals and patients more ability to bring new medical technologies to health care professionals and patients more rapidly, through a strengthened program that can meet the public's expectation that the medical devices they use are safe and effective. These resources will also help us meet the challenges now facing us from the medical device industry that include increasingly cutting edge and complex technologies that are being applied to current medical device products being developed and a shortage of the right scientific expertise needed to review these products. We must ensure that our science base is up to date, that our reviewers receive appropriate training, improve our outreach to industry and other stakeholders, and improve our review information system. We believe the increase will work to enhance our infrastructure, respond to the expected growth in the number of PMA applications the Agency receives, and improve our performance.

The request also includes $23.225 million in other user fees for mammography inspections, export certifications and color certifications, an increase of $.735 million over fiscal year 2003.

Proposed User Fees—Animal Drug Review User Fees $5 million

A new user fee is proposed for the review of animal drug products. This proposal is patterned after the successful Prescription Drug User Fee Act, PDUFA that has enabled FDA to add over 1,000 employees to the drug review process over the last 10 years. With this $5 million request, FDA would improve and expedite the review of animal drug preapprovals.

Closing

I thank you for your commitment and continued support of FDA. We all have a shared responsibility of bringing to American homes safe, varied and plentiful food, and products devoted to providing the public with a healthy lifestye and healthy choices. I look forward to a long and harmonious working relationship with you, the Congress and other interested parties as we collaborate to promote and protect the health of our people.

MEDICAL DEVICE USER FEES

Senator BENNETT. I am sure it will come as no surprise to you that since assuming this position, I have heard from a lot of folks about MDUFMA, the Medical Device User Fee. I have tried to understand this. Let me see if I have got it right.

The medical device people agreed some time ago that they would start to pay a user fee if in response they would get faster turnaround times, the argument being, well, we just don't have the resources within FDA to give you the turnaround times on approvals that you say you need and they say it is so important. Their reaction was, it is so important to us to get rapid turnaround times for our applications that we will pay for it.

And so a deal was struck whereby they would pay, and let me see if I have the numbers right, $150 million in user fees over the next 5 years and the government would match these funds with a $15 million increase for the Center for Devices and Radiological

Health in each of the fiscal years 2003, 2004, and 2005. In other words, the user fees, if I can add it correctly, add up to $150 million and the Feds say, we will put in another $45 million, so we approach an additional $200 million to try to get faster service out of the government.

This was enacted into law in October of 2002, after the 2003 budget request was received. Now, my predecessor as chairman of the subcommittee, Senator Cochran, was unable to get more than $4 million in 2003 as a start on this, but that was a good start and a significant downpayment of the $15 million that was envisioned.

So now we get your budget and you are increasing it by $1 million and we are going the other direction. I understand, having been in the executive branch, the kinds of pressures that you are under from OMB and the kinds of things that happen, and I am not going to ask you, did you recommend that we were going to the $15 million and then did the people at OMB cut you back. That is the kind of internal negotiations that go on and I am not going to go there.

But one of the things I learned as a businessman is that a deal is a deal, and we are in a situation where the industry is coming up with an additional $150 million in user fees and someone in the budgetary process is saying, that is wonderful. Let us take that $150 million and spend it someplace else. In other words, money is fungible and if we have got an extra $150 million coming in from another source, we will use that to offset money that we would otherwise have spent to try to get this up here. As you can understand, these folks feel somewhat badly used.

So my question to you is what your suggestions are as to how we get out of this and if this subcommittee were to earmark some additional money to get close to the $15 million that was agreed to, can you help us find the offsets as to where it might come from?

Dr. MCCLELLAN. Mr. Chairman, MDUFMA is one of those terms that, probably like you, I hadn't heard much before coming into government work and starting to work on important issues related to the development and use of new medical technologies. But I think your understanding of the program is extremely good and I think your awareness and attention to this issue is extremely important.

There are many breakthroughs occurring in medical devices today. We recently approved a new drug-eluding stint that will significantly reduce the rate of complications after many heart procedures for the millions of Americans suffering from heart disease. We need to make those newer, safer, more effective treatments available to the public as quickly as possible.

The FDA has long supported user fee programs like MDUFMA in other areas of medical technology. We have got a prescription drug user fee program that works for drugs and biologics extremely well in helping us reduce approval times and getting safe and effective products out there to the public more quickly, and we support it and we still support an effective medical device program. We are trying to get the Senate to act very soon on an animal drug user fee program, as well.

This is an issue where from—I know you are experienced in the executive branch and in the Senate—you are right, a deal is a deal,

but sometimes new programs take a little bit of extra effort to get off the ground effectively, and I want to tell you right now that I at FDA, Secretary Thompson at the Department, and everyone in this administration who cares about this issue is fully committed to the goals of the Medical Device User Fee Program.

At FDA, what we have done is we have already started to hire some of the new people under the user fees that the companies are paying now. We are doing this with the full expectation that this is going to be a long-term program, that it is going to lead to some significant improvements in our approval times, which are too long today for priority medical devices. So we have got about 40 hires that we are in the process of making now for medical reviewers and other experts to help us improve the job that we are doing on medical devices and we are making some longer-term plans to help make sure that this program works.

This is a matter that, as you know, has been under considerable discussion recently with the industry, with many people in the administration and many members on the Hill, and I want to thank you and I want to thank Senator Cochran for their efforts in helping to get this program off the ground.

I appreciate your telling me you don't have to hear from me about discussions internally with OMB, but I think I can tell you that I have had a lot of discussions with senior officials in OMB and I think I can tell you that the entire administration is committed to making sure this program works, that it is made permanent, that we do get the significant kinds of improvements in device review performance that the program envisions, and we have got a little bit more work to do to get there.

So we intend, OMB intends, the entire administration intends to work closely with this committee and with other key appropriations and authorizing committees in Congress to make this program work.

With respect to earmarks, that is obviously something that is going to continue to come up in these appropriations discussions and I know and trust that we are going to have ample opportunity to talk with you about ways to make this program happen without getting in the way of other key priorities for the FDA. As you well know, we have got a tremendous amount of responsibilities at the agency. We have got a budget that we are trying to do the most with in order to meet those responsibilities and so we need to be very careful about any kind of earmarks that would take funds away from other key priorities.

So I can't tell you right now that we are going to have that $15 million right now in the budget for this year. I can tell you that we, that OMB, that everyone in the administration is committed to finding a way to make this program work, to make it sustainable, make it permanent, make it have triggers that won't need to kick in because we are meeting our performance goals, and it is going to take a little bit of work in the weeks and months ahead to do that, but we are going to do that.

Senator BENNETT. Well, thank you. Talk about imposing new user fees in new areas will impact how well those user fees are responded to, because if, indeed, you have the reputation of inducing, if you will, people to agree to a user fee by saying, and we will

raise ours on this side if you raise yours on yours, and then when that user fee turns into really nothing more than a tax that goes into the general fund and gets used fungibly for something else, it is going to be very difficult——

Dr. MCCLELLAN. The companies that are paying the user fees have an expectation that they are going to get significant performance improvements in response to that and we have got to fulfill those expectations.

Senator BENNETT. You have got to fulfill that, and I will do what I can to try to help——

Dr. MCCLELLAN. I appreciate that, and I will look forward to working with you on this in the weeks ahead.

DRUG REIMPORTATION

Senator BENNETT. My time is going down, but very quickly, this isn't "beat up on Canada" day, but could you talk about the reimportation of drugs and the safety of drugs, that people go to Canada to buy drugs and then bring them back into the United States.

Dr. MCCLELLAN. We are working hard on that issue, as well. As you probably know from our—as I am sure you know from our previous discussions, one of my top priorities at the agency is to do all we can to do our job more efficiently, because in many ways, in reducing the costs of the drug development process, making generic drugs more quickly available, helping to prevent medical errors, getting consumers better information about how to use pharmaceuticals, are many things that FDA can do to help drive down the costs that people are paying. The problems with affordability of medical care today are very much in front on my mind and the mind of millions of Americans, so many things that we are doing to help people reduce costs of drugs while still making sure they have safe and effective drugs.

Where I have concerns is when people have to cut corners, when, because of affordability concerns, they take risks that involve the use of products that may not be as safe or as effective. And the problem with reimported drugs that come into this country outside our regulatory system is that we can't provide assurances about the safety or effectiveness of those drugs. Because I care a lot about this, we have had a lot of discussions with the Canadian authorities in recent months about steps that might be possible to take to provide more of those kinds of assurances.

Canada recently issued a guidance about the safety and effectiveness of drugs that come through Canada. But in putting that out, they also clarified in a letter to the Washington Post just yesterday that they can't assure the safety of imported drugs coming illegally into the United States, that is, coming in outside of our regulatory system. We can't, either, because they are outside of our regulatory scheme.

And so there is a real concern there. We have got to find better ways to make affordable treatments available. Reimportation of illegal drugs, or importation of illegal drugs, since you often can't tell the difference, is not a safe and effective solution.

Senator BENNETT. Thank you. Senator Kohl.

CHRONIC WASTING DISEASE

Senator KOHL. Thank you, Mr. Chairman.

Dr. McClellan, yesterday in the Washington Post, it was reported that in Canada, there was a large elk herd living near the area where the infected cow was found and that chronic wasting disease was common among that elk herd. When asked whether or not chronic wasting disease could have jumped from the elk to this particular cow and turned into mad cow disease, Dr. Lester Crawford, your Deputy Commissioner, stated that there are no known cases of this happening, but, and I quote him, "you really can't entirely predict what a prion-related disease will do."

Obviously, this statement is alarming because in States like Wisconsin, where CWD has been found, we also have a large cattle/cow presence. So do you have some clarification or some words of comfort that you can offer in addition or in correction, to some extent, to what was said by your Deputy Commissioner yesterday?

Dr. MCCLELLAN. Senator, it is a good question, and let me just be very clear that what I can say is based on the best and latest available science, and what the science tells us is there is no evidence that chronic wasting disease, which is another prion disease, has any association with BSE, has jumped species or in any way could cause BSE in ruminant animals.

As you know, the elk and game animals in which CWD is present are different from the ruminant animals that are carriers and that are subject to BSE. They are different illnesses and there is no evidence of transfer between species. Moreover, as I understand the facts, that elk herd that you mentioned in Alberta was something like 100 miles away from where the affected cow was, so no opportunity there physically for any kind of transmission to occur even if there was some evidence that transmission could occur, and as I said, there is no scientific evidence that it does occur. So at this point, I don't see any evidence that CWD has any association or connection to this BSE case.

Just an added word about my Deputy Commissioner. He is one of the foremost experts on animal health in public policy today and I think the country can be very confident that FDA is taking effective action on these important issues related to BSE and CWD in Wisconsin as a result of his contributions and hard work at the agency, and his views on this issue are exactly the same as mine.

Senator KOHL. I do appreciate that and the clarification is very helpful. Thank you very much, Mr. Chairman.

Senator BENNETT. Thank you. Senator Cochran.

Senator COCHRAN. Mr. Chairman, thank you very much for the good job you are doing, Mr. McClellan.

Dr. MCCLELLAN. Thank you, Senator.

RELATIONSHIP WITH THE DEPARTMENT OF HOMELAND SECURITY

Senator COCHRAN. You are off to a good start and we appreciate that good effort.

The Department of Homeland Security has been created and with it has come some new responsibilities. One example is transfer of some authority from the Animal and Plant Health and In-

spection Service to Homeland Security and Plum Island, the facilities there.

The question is, though, since FDA, your agency, and the Department of Agriculture continue to be responsible for food safety, however, to what extent are you working with the Department of Homeland Security to ensure that you have whatever information you need that they may be able to share with you so that your agency and the Department of Agriculture can continue to carry out your responsibilities to quickly identify and respond to outbreaks of foodborne diseases?

Dr. MCCLELLAN. Senator, we are working extensively now with the new Department of Homeland Security. This is actually a big boom for food security efforts in this country. The Department has a strong commitment and some important expertise. One of their under secretaries comes from doing security work for a major soft drink company, for example, so they have got some important expertise to contribute in food and drink security, as well, in this country.

I want to thank you for your efforts now on homeland security. We certainly miss you here. No disrespect to the new chairman, but it is very useful from my standpoint to have somebody in your position who understands the complexity of food security issues and all of the resources that we have available and where we need to improve them to keep the country's food supply secure.

So far, I think we are off to a good start. The Department of Homeland Security is staffing up now. We have regular interagency meetings with them on food security issues and also agriculture security issues that involve USDA, as well. We are also supported in this effort by the White House's Homeland Security Council, which has a number of specific directorates that work on issues like developing countermeasures and protecting the infrastructure that bear, as well as public health, that bear on supporting our activities.

Some of the specific issues that you mentioned, such as making sure that intelligence information is shared effectively, making sure that the USDA and FDA are using the same kinds of simulation models and expert input in developing our strategies for our respective roles in protecting and securing the food supply, in these and many other areas, the Department is very helpful and I will look forward to continue working with you to make sure that whole process of coordination and support works well.

Senator COCHRAN. In this budget that is before us for review, is there funding requested to support these interactions?

Dr. MCCLELLAN. There is substantial new funding requested in this budget for our food security efforts, over $20 million in new funding in the 2004 budget. That includes funding that is going to go to States to help them improve their inspections related to food security issues, help improve our nationwide food laboratory network. We have recently announced some other programs with CDC and the like to do that, as well. We are implementing new information systems. We are taking a lot of steps.

In all of these areas, homeland security coordination is built in. Our methods of implementing all these steps involves some important input from Homeland Security. So, for example, in the work

that we are doing with the States, the overall guidance for that work comes out of interagency working groups that the Department of Homeland Security participates in and the White House Homeland Security Council chairs in many cases.

DRUG COUNTERFEITING

Senator COCHRAN. The chairman asked you about the reimportation of drugs from Canada and what your views were about that. We also had brought to our attention last year, your predecessor came to a meeting with Senator Kohl and me about the dangers associated with counterfeiting of drugs and the dangers in policing that, that over-the-counter drugs in many instances had been counterfeited in countries outside the United States and that customers were now buying drugs off the Internet from overseas sources.

What are the dangers associated with that and do you have in your budget any funding requests that would help you get the word out or publicize the danger so that consumers would be aware of the dangers in connection with these practices?

Dr. MCCLELLAN. The dangers are serious, and I just want to give you a "for example." Yesterday, we were involved in a criminal investigation and operation in the State of Florida that took action against some individuals who are involved in manufacturing a counterfeit drug and trying to sell a counterfeit version of a drug called Procrit. It is one that is potentially life-saving for people who have low blood counts and this counterfeit version was not an effective drug. It was actually non-sterile water which could have caused infections as well as not providing the intended treatment.

I am worried about this. We are seeing more of it as the technologies available to people who don't have the best interests of the American public at heart get better and get used more widely, and as people worry more about the costs of prescription drugs, we are seeing more efforts to introduce counterfeit drugs into the system as well as more efforts by illicit Internet groups. For example, we announced an action recently involving a company in Belize that was offering products over the Internet. They didn't obviously identify on their site that they are in Belize. We had to trace back the site's address and so forth. Obviously, we can't provide any assurances about the safety or effectiveness of these products.

We are devoting some additional time and effort and attention inside the agency to find better ways, working with everyone involved in the drug distribution system, to protect Americans from these growing threats, and I think we are going to be able to do that in the months ahead.

But part of the effort here is also publicizing information. We put out a number of brochures and educational materials that can provide guidance to people about how they can buy drugs safely over the Internet. There are some perfectly legitimate providers there and they can provide access to treatments that may be hard for people to get if they live in rural areas and the like. But they need to follow the advice that we give to avoid some of these kinds of illicit drugs that come outside of the system of drug regulation that the FDA provides, and outside that system that we are very determined to protect the integrity of, outside that system, we can't assure safety and effectiveness.

We are working with pharmacies. We are working with various public health organizations to try to get this message out, and I think we need to do more of it. It is a growing concern at the agency.

Senator COCHRAN. Thank you. Mr. Chairman, my time has expired. I do want to submit a few questions for the record, particularly one related to the Center for Food Safety and Applied Nutrition at FDA and its collaboration with the National Center for Natural Products Research at the University of Mississippi.

Dr. MCCLELLAN. That has been a very effective collaboration for us, learning more about dietary supplements, which is a big concern of mine. Thank you.

Senator BENNETT. The questions will be included in the record.

ANIMAL FEED RULE COMPLIANCE

Senator JOHNSON. Thank you, Mr. McClellan, for joining us this morning. The references to reports as of March 23 relative to 14 percent of rendering facilities handling material, prohibited ruminant feed, not having a system to prevent commingling, and 33 percent of non-FDA-licensed feed mills having not labeled their products came from a letter from a group of consumer organizations sent to USDA Secretary Veneman and HHS Secretary Thompson just yesterday. It is my understanding that your assertion is that their numbers are simply incorrect.

Dr. MCCLELLAN. Well, they are outdated. My understanding is that their statements were based on a GAO report from 2002, which, in turn, was based on data and information collected in 2000. I think the GAO report highlighted the need for us to be particularly vigilant in this area because the food ban is absolutely one of the critical firewalls of protecting Americans and protecting our cattle if there were ever a case of BSE discovered in this country. Remember, because of the way, as you well know, because of the way that BSE is transmitted, it has to go through the food supply, through the feed that cows eat. And so you have to have an infected cow being rendered into animal feed for this ban to have a protective effect.

Right now, we don't have any infected cows in the United States, despite an awful lot of testing by USDA of at-risk animals, and so this ban is an additional firewall of protection for the country and we need to make sure that it works. And that is why, over the past year since that GAO report, we have really stepped up our efforts and we would be happy to provide your staff with the full set of information, the latest numbers. But we are at over 99 percent substantial compliance with the feed ban and we are aiming for total compliance and we are going to do everything we can to get there.

ANIMAL FEED INSPECTIONS

Senator JOHNSON. It is my understanding that 80 percent of the feed mill inspections are handled at the State level and you only really have about ten personnel involved. Are you comfortable with that——

Dr. MCCLELLAN. Well, we have more than——

Senator JOHNSON [continuing]. The State-FDA partnership?

Dr. MCCLELLAN. We have more than ten personnel involved in this inspection activity. As I mentioned earlier, we spend over $22 million of our budget on these BSE-related activities and close to $11 million of that is for field inspection activities by our personnel.

We do rely a lot on our State partners in this effort and that is why we put a lot of work into training and monitoring programs to make sure they are doing the job. We have conducted a massive training program to ensure that State inspectors are every bit as informed as our FDA inspectors and we also have held training programs at several locations throughout the United States to give them an opportunity to participate actively in these education activities.

In addition, we have standardized and computerized the inspection forms to minimize inconsistencies and minimize human errors and we have implemented computerized checks in case we see something that shouldn't be there. We have improved our whole computer information support system for this very important activity.

All of these activities were implemented in response to the kinds of concerns that you raised. I want to thank you for that, and that were raised by the GAO report, and I want to continue to work closely with you and your staff to make sure we are taking all necessary steps to make sure that this feed ban works effectively.

Our staffing levels are at a much higher level than ten for this effort. For example, in the 2002 budget where we started establishing this $22 million line item, I think we had close to 200 staff in activities related to this BSE program. But like I said, we will be happy to follow up with you and your staff to make sure we are doing everything appropriate on this very important issue.

Senator JOHNSON. Very good. Senator Dorgan is here, and he may have some questions about the Canadian reimportation of prescription drugs issues, but I do want to just very quickly allude to the fact that I have a great number of my constituents who rely on a regular basis on purchasing prescription drugs from Canada and they are FDA-approved, branded, and very effective drugs.

It seems to me that it should not be rocket science to figure out a monitoring system. Granted, this is a very roundabout way of dealing with America's prescription drug pricing issues, but it seems to me that in the meantime, the alternative, although you talk about risk of drugs from Canada, the alternative is an even larger risk that people simply are not going to take prescription drugs because they can't afford them. My constituents literally are choosing between groceries and staying on their prescriptions. This is not only a crisis, it is an urgent crisis.

In a more perfect world, we would do a number of things legislatively to address the problem. America remains the only major industrialized society in the world that does not negotiate on behalf of its citizens a better price. And so my constituents are buying these drugs at less than half the price. Not only that, they are going to Mexico, which I would caution my citizens about. But I have my constituents telling me that they snowbird to Texas to pay for their entire stay on the prescriptions they buy in Mexico. It has become, as you know, a bit of an industry in both those countries.

I have had people tell me that at one time it used to be the border towns were various kinds of tourist attractions, now it is pharmacia, pharmacia, pharmacia as they go across the border. And even in Mexico, although I would urge caution there, a lot of people are staying alive literally because they are buying their drugs in Canada and Mexico and not paying the prices that they have to pay in the United States.

I just simply want to tell you what you already know, but also urge you to work with us constructively to devise a system whereby we can provide whatever additional assurances, particularly relative to Canada, that reimportation would allow us to do. It is a band-aid in a way because we need to address this in the context of Medicare and other kinds of things, but we will need the FDA's cooperation for that legislation which I am convinced will pass once again to make that work.

Let me just ask you very quickly, because my time is expiring, make sure that I understand on the user fees for medical devices. You are using 100 percent of the user fees towards the purpose of expediting that program? You are not pocketing the money and using it, as Senator Bennett caused me some concern, talking about the money being fungible and heavens knows what the money is being used for, as simply another tax. While we are not fully matching it, you are at least using this new revenue flow, revenue stream, for the purpose it was designed, do I understand you correctly on that?

MEDICAL DEVICE USER FEES

Dr. MCCLELLAN. You understand us correctly. The budget was passed late this year for 2003. As soon as it was approved back in February, we started the process of hiring the new reviewers and other medical experts who will make this program work better. We have got a process ongoing now. It is going to get 40 more expert staff into the program as soon as possible to improve the way that we are handling device reviews.

Like I said before, we are going to build on that effort. We want to make this program permanent and successful.

Senator JOHNSON. My time is expired. I do have a couple other questions that, with Mr. McClellan's agreement, I would like to submit to the FDA.

Senator BENNETT. They will be submitted. We will have a second round, if you desire.

Senator JOHNSON. I am going to have to excuse myself, unfortunately, fairly soon here for, as usual, other conflicting, overlapping investigations, but thank you, Mr. Chairman.

Senator BENNETT. Senator Dorgan.

DRUG REIMPORTATION

Senator DORGAN. Mr. Chairman, thank you. Let me follow up on the questions that my colleague has asked with respect to reimportation.

I want to talk to you about a February 12 letter from the FDA. First, let me tell you about a woman named Sylvia Miller who I accompanied, along with other senior citizens, to a one-room drug store in Emerson, Canada, five miles north of the North Dakota-

Canadian border. This drug store in Emerson, Canada, was visited by a group of senior citizens accompanied by myself. Sylvia Miller was among them. She purchased Coumadin, Zestril, Glucophage, and Serevent, among other things, and saved about $150 by buying her medications in a small one-room pharmacy.

I didn't think and don't think, and she didn't think, and I expect you don't think there was any concern about tainted medicine or counterfeit medicine. This is a chain of supply that is almost identical to ours and she was purchasing at a licensed pharmacist in Emerson, Canada.

February 12, your agency sent out a letter that was signed by——

Dr. MCCLELLAN. Mr. Bill Hubbard, probably.

Senator DORGAN [continuing]. By Dr. Bill Hubbard, and let me just read what it says. It talks about reimportation. It says, those who can be found civilly and criminally liable include all those who cause a prohibited act, those who aid and abet a criminal violation of the act or conspire to violate the act can be found criminally liable.

The result of this letter is that Blue Cross-Blue Shield of North Dakota then put out a missive in North Dakota saying, we can no longer cover with our insurance policies the purchase of prescription drugs in Canada by citizens who have our policies. So North Dakotans are now told because of your February 12 letter that prescription drugs purchased in Canada will not be covered by Blue Cross-Blue Shield.

Was that the intent of this letter? Would you really have intended, for example, to tell a Sylvia Miller, if she had Blue Cross-Blue Shield, if you drive to Emerson, Canada, and buy a prescription drug from a licensed pharmacist, it is FDA's judgment that an insurance company could be held criminally liable for aiding and abetting that and, therefore, they should cut off insurance coverage for those prescription drugs?

Dr. MCCLELLAN. That is a question that several insurance companies have asked following the letter. My understanding from our discussions with a number of insurance companies, the American Association of Health Plans, and others is that there are no companies out there actively encouraging people to go to Canada to buy drugs.

Senator DORGAN. That is not the question. You are not answering the question I have asked.

Dr. MCCLELLAN. Well, you know, what we did there was restate what has long been FDA policy, and the FDA policy is, as you know, Senator, that personal importation of drugs is allowed. We have got a lot of good medical treatments out there and they are not affordable because Medicare does not have decent prescription drug coverage and it needs it now, so I have got a lot of sympathy for your constituent. But FDA has a policy on personal importation. If people go across the border and bring back a personal supply, even though that is technically illegal, we are not enforcing the law against those individual persons.

So when they go over and they go to a Canadian pharmacy that provides drugs to Canadians, and they are not FDA-approved but they are approved by the Canadian agency, I can understand how

she would, in the circumstances she is in, because Medicare doesn't cover drugs, would feel like that is what she has to do.

That is very different than an insurance company going out and actively encouraging people to buy drugs illegally over the Internet.

Senator DORGAN. Mr. McClellan, I am sorry. I have limited time. You are answering a question I haven't asked you. There is no evidence that any insurance company in the history of America has encouraged people to go across some country's border to buy prescription drugs. I have never even heard of that. I am asking you——

Dr. MCCLELLAN. That is what I am saying. That is the relevant issue.

Senator DORGAN. So what is the deal? Why are you talking about that? I am asking you a very specific question. I would like an answer, if you could.

Dr. MCCLELLAN. Because what the companies wanted to know from us, and what we clarified since that letter, is we are not actively encouraging any Americans to go anywhere to buy prescription drugs illegally outside the system. We are taking all reasonable steps to make sure that people are getting legal treatments, FDA approved, safe and effective treatments. Do we need to do anything else? And the answer is no. They should just continue following the policies that they have been following.

Senator DORGAN. Let me re-ask the question, then.

Dr. MCCLELLAN. And I will re-answer the question.

Senator DORGAN. You have not answered it. You have not answered it, with all due respect. The question is this. If Sylvia Miller is able to go to Canada and bring a personal supply of drugs back, a 30-day supply of drugs, for example, or a 90-day supply of drugs, whatever that might be, is it your intention to threaten insurance companies who might cover that because they have a policy that covers prescription drugs for that particular policy holder? Is it your intention to say to insurance companies with the February 12 letter, don't you dare reimburse your members, because if so, you may be abetting this and you may be liable for criminal prosecution? Is that really your intent?

Dr. MCCLELLAN. Our intent, and our discussions with the industry, and our understanding of the way that the industry has responded to this——

Senator DORGAN. Let us talk about your discussions with the industry, then, because——

Dr. MCCLELLAN [continuing]. Is that no companies are changing their policies—no companies have had to change their policies about coverage because none of them are actively encouraging people to go get prescriptions. Is it possible that under a policy someone goes across the border and gets a prescription and gets it covered? Certainly, it is possible, but that is different from a company actively encouraging people to use potentially unsafe drugs.

Senator DORGAN. Do you believe an insurance company should prohibit coverage when an American senior citizen, for example, goes over and brings a prescription drug back and is allowed to bring it back by your own testimony? Do you believe the insurance company should prohibit payment for that, because that is what is

happening. Blue Cross and Blue Shield of North Dakota has put out an announcement, "We will now no longer cover these."

The fact is, we are not talking about a lot of money. We are not talking about a lot of consumers. But the fact is, they have cut this off because of your letter and I am asking whether the FDA letter intends that to be the case.

Dr. MCCLELLAN. I am happy to talk with any company in this country to clarify what FDA's policies are and are not. This is not something that is aimed at your constituent going across the border to go to a reputable Canadian drug store and personally buy prescriptions that she thinks are safe.

There are some real concerns, and I am sure you wouldn't want insurance companies or anyone else to encourage Americans to buy drugs over the Internet where the drugs may not be safe or they are not approved by us or the Canadians have explicitly said they can't assure the safety and where the consumer may not even know where the drug is coming from. I am sure that is not what you would want us to encourage.

Senator DORGAN. Different subject, but thanks for raising it. My question remains, do you want the FDA to be on record, which it is, telling an insurance company that they may be criminally liable, so be sure and tell your policy holders they will not cover prescription drugs that they now purchase in a trip to Canada, because that is where we are and I am asking whether that is what your intent is and you have not yet answered what——

Dr. MCCLELLAN. I will tell you what my intent is. What I hope people are telling their policy holders is the same thing that we are telling the public, which is that drugs that are not approved by the FDA, that are not legally obtainable in the United States cannot have safety assurances that we would vouch for. We cannot assure that they are safe and effective.

We have had a lot of discussions with the Canadian government about this, Senator, in recent months because I am very concerned about the safety of drugs that all Americans are doing, and the upshot of those discussions is reflected in what the Canadian government said yesterday in the Washington Post, is that they can't assure the safety of drugs coming to Americans from outside the United States. We obviously can't assure it because it is outside of our regulatory sphere. So this is a real area of concern.

I think what this also highlights for your constituent is that it would be very important for the Senate to act as quickly as possible to pass a real Medicare prescription drug benefit so that she can get affordable medications. There are too many Americans like her who are facing a choice between buying drugs that they can afford and buying drugs that they can be sure are safe and effective and do what the drugs need to do. That is not a good position for health policy to be in and I am sure we share the goal of getting this addressed as soon as possible.

Reimportation of illegal drugs is not a cornerstone for a safe and effective public health policy in this country. It shouldn't be. We can do better and we should do better.

Senator DORGAN. Well, the great part about this country is you and I have the right to disagree about that. I profoundly disagree about what you have just said. When Sylvia Miller goes to a phar-

macy in Emerson, Canada, if you know anything about the chain of supply in Canada, and you do, you understand that the purchase of Coumadin in that drug store is as safe as purchasing Coumadin at a drug store in downtown Washington, D.C. You know that and there isn't any way you would try to refute that. But that is not what I am asking about——

Dr. MCCLELLAN. And I am not——

Senator DORGAN. I am asking a very simple question of you. Is it——

Dr. MCCLELLAN. And just to be clear, I am not refuting that a drug that Sylvia Miller goes and buys in a Canadian pharmacy is very likely to be safe and that the Canadian government does a very good job of assuring the safety and effectiveness of medications for their own citizens purchased in their own pharmacies.

The problem today is that the vast majority of Americans who are buying drugs from outside our regulatory system are not doing what Sylvia Miller does. They are buying over the Internet from sites that may be in Canada, that may not. We have seen a lot of the products coming into the country. In many cases, they are not labeled properly. They are the wrong amounts. They don't come with the risk management and warning information that a doctor and pharmacist in this country would provide. This is not a safe and effective medical system for providing prescription drugs and we need to do better.

Senator DORGAN. Well, the pharmaceutical industry spends a great amount of money advertising your position, but frankly, I am talking to you about a narrower issue here this morning and I have not yet received an answer.

Dr. MCCLELLAN. Maybe the best thing.

Senator DORGAN. Wait a minute. Let me finish the question. Do you believe that Blue Cross and Blue Shield of North Dakota should cover a prescription drug that is an FDA-approved drug purchased at a drug store in Emerson, Canada, brought back for personal use by a senior citizen in North Dakota? Should Blue Cross and Blue Shield cover that if that person has a policy that provides prescription drug coverage, or should Blue Cross-Blue Shield be potentially liable for criminal sanctions, according to your letter? Which do you believe?

Dr. MCCLELLAN. I don't think that there is anything in our letter that expressly and in general prohibits Blue Cross-Blue Shield of North Dakota from covering a prescription that one of their members may have purchased in Canada on a personal use basis. That is consistent with our policy of personal importation.

That is very different from Blue Cross-Blue Shield of anywhere encouraging or advocating or taking steps to promote the use of illegal pharmaceuticals in this country, and I would be happy, again, just to make sure—I am sorry we are not quite connecting on this because it is an important public health issue—I would be happy to talk with representatives from this company and get them in touch with our staff to clarify exactly what the letter means.

We have had these discussions with insurance companies and I am very confident that most insurance companies in this country are interested in paying for drugs that are safe and effective and that promote the public health as a result. And so I don't think

there is any conflict between their policies and what our letter says and I am happy to get our staff to verify that Blue Cross of your State is not an exception to that rule.

Senator DORGAN. Mr. Chairman, thanks for your patience. If you are saying that there is nothing that prohibits this insurance company from covering a prescription drug purchased from a pharmacy in Canada, then we need to resolve it with this insurance company. We have got some folks out there who would expect to have their prescription drugs covered and they are now not covered because of your February 12 letter and because of its interpretation. I just read part of it. If I were the insurance company, I would interpret it the same way.

But if you say that is not what you intend, you don't intend to prohibit this company from covering that circumstance I described, if that is the case, then let us do a U-turn on this letter, or at least redescribe what you intend in the letter so that Blue Cross-Blue Shield of my State knows that.

Look, I don't know you from a cord of wood. I mean, we don't exchange Christmas cards and you are probably extraordinarily competent. In fact, a colleague of mine was just telling me that they have very high regard for you. What angers me is that people who can't afford to get knocked around in this system all the time, just all the time. The woman I discussed here is just one, but she is trying to live on a very small amount of money, trying to buy prescription drugs. She has to take ten of them. And so in this circumstance, she was trying to access a less expensive prescription drug that she knows and I know is safe because the chain of custody in Canada is identical to ours.

Frankly, I just get angry when I see this letter, which is parroting the pharmaceutical industry's advertisements about why we shouldn't have the ability to go to Canada. Why shouldn't there be free trade in prescription drugs, as long as we can guarantee safety? I don't think there is any question that we can.

Do you know that almost every day, a semi-truckload will come to the U.S. border with Canadian meat. Do you know what they do? They say, well, if it was inspected in the Canadian plant, it is good enough for us. They run it right through the border. But we can't do that with prescription drugs that go from a manufacturer that is inspected by the FDA, a drug that is approved by the FDA, goes into a chain of custody from the manufacturer to a wholesaler to the drug store that is licensed. We can't do that? Of course, we can. You know that.

Look, I think I have made my point. I think you have told me some new information here finally. I don't intend to be rude, Dr. McClellan. I want you to do your job and do it well. I want the FDA to be on the side of consumers, and Mr. Chairman, thank you for giving me the opportunity.

Dr. MCCLELLAN. Mr. Chairman, if I could have just a minute——

Senator BENNETT. Surely. There is no one waiting for a third round.

Dr. MCCLELLAN [continuing]. And I do want to thank you, Senator. I mean, look, we are both frustrated about this issue. Drugs should be more affordable in this country. I am trying to do every-

thing I can at FDA for our part of getting the costs of drugs and other medical treatments down.

But as FDA Commissioner, I have to pay a lot of attention, for the reasons that you just mentioned, to making sure that the treatments are safe and effective and to protect the integrity of the assurances that we give to the public about the safety and effectiveness of drugs.

I am not a cord of wood. I am a doctor and I am a health policy person, but I am not a lawyer. So we probably need to get our lawyers to talk to the company lawyers and just make sure we get the clarification here. I think everybody has got the same goal of getting safe and effective treatments to people at the lowest possible cost, and I will get you on our Christmas card list.

Senator DORGAN. Well, Commissioner, I am not a lawyer, either, so we have something in common. Let me make sure you are on my list, as well, and we will exchange this coming year and begin to visit. Thank you for answering the question.

Senator BENNETT. I am not a lawyer, either, so that brings us all around.

Thank you very much for your testimony this morning. One or two quick things in conclusion.

I think one of the values of this hearing is that we have seen a greater degree of coordination about BSE statements coming out of the government than has been the case in the past, and I would hope you and the folks at USDA and anyone else who is involved could talk to each other as well as talk to the press with the responses that are being demanded because it is very helpful to get the total picture.

The additional information you have given about what happens to a slaughtered animal whose carcass is then rendered and that is avoided getting it into feed that would go to a ruminant animal is something that was not in the USDA statement, not that they avoided it, but it was simply they dealt with their side of it, you dealt with your side of it, and putting the two together should have a much greater calming effect than taking either one by itself.

So I would hope, to the degree you can, there could be some coordination there in the public statements on this.

Dr. MCCLELLAN. Absolutely.

NUTRITION

Senator BENNETT. And finally, you heard my conversation with Under Secretary Bost, which, as I say, I touched one of his hot buttons. You have a role in the question of nutrition and, of course, as we get into the whole issue of obesity, we get into the area of drugs because a lot of people are treated with drugs, either in an attempt to deal with conditions that trigger overeating—insulin is a very, very major player in the whole question of weight management.

Indeed, that is the thing that was driving this book. The woman was an endocrinologist who was dealing with diabetics and with insulin. That led her into her conclusion that too high an intake of carbohydrates was part of the problem and her subsequent examination of the pyramid, and the same thing is true with Dr. Sears

and the writing that he has done in his book "The Zone" and the people who are following that diet.

Can there be some greater coordination, a greater breakdown of silos, if you will, between FDA and USDA on some of these nutrition issues so that we can come to the Federal Government as the final arbiter that says, this is the way Americans should eat. These are the manifestations. USDA, as they construct the pyramid, at least from my perception, probably is a little isolated from the endocrinologists, the study of insulin, the study of impact on blood sugars and drugs that are created to deal with that, and a little cross-fertilization in this area could be very helpful.

Also, do USDA scientists—you say you are a doctor. There is a whole series of studies that are done in NIH that could impact our whole approach to nutrition. One of the things that is frustrating to me as I come into government is the discovery that we do live in a world of silos and stovepipes and particularly in the budgetary process. We appropriate money for this and they are studying something. Then we appropriate money for this and they may be studying the same thing from a slightly different point of view. Then we appropriate money for this and they are studying the same thing from a slightly different point of view.

We could not only save some money, but more importantly, we could get much better results if the stovepipes kind of disappeared and people began to coordinate and cooperate and just talk to each other across agency lines.

So I would leave you with that admonition at the close of the hearing here. Any response? No response is necessary, but if you have any, of course, I would be happy to receive it.

Dr. MCCLELLAN. I would be glad to, at the risk of taking up a couple more minutes of your time. This issue of coordination and the importance of good diets and promoting the public health is a top priority of Secretary Thompson's. He has made many of the same points that you have.

Public health is a very complex topic, public health and diet, and there are some good reasons to have some specialized expertise focus in different places. But I particularly appreciate your emphasis on making sure that each of these silos of expertise is working together effectively towards the overall public health goals that we need to support, and I agree with you, as well, that there are few more urgent than trying to do more to help people find safe and effective ways of watching their diet in a way that reduces obesity.

Right now, we are clearly doing badly. We have already gone over the statistics. Under Secretary Bost cited some of them. We need better treatments. Many people today are turning to smoking cigarettes or using unproven dietary supplements in an effort to lose weight and that is just not a safe way to go about this.

The main public health message that we have learned from the various types of research is pretty simple at a basic level, which, as Under Secretary Bost said, it is what you take in and what goes out—in terms of calories and what goes out in terms of energy expenditures that contribute to whether you are gaining or losing weight or not, and while we at FDA don't regulate those kinds of books that you put up there, that is not a medical product, I would

also add the admonishment that if it sounds too good to be true, it probably is.

For some of these diets, even though they have been shown to have some short-term effects on weight, what you really need is a sustained long-term weight loss program and a sustained long-term balanced diet, with calories in equaling calories out, and most of those diets don't do so well from a long-term standpoint, which is what you really need to improve health.

And to do that, we need to find some better approaches. We are working on new medications at FDA. One of our priority areas for new guidance to industry is in obesity, is in better obesity treatments, and that is an effort that NIH is working closely with us in. We are trying to encourage industry to do more to compete about the health consequences of their foods and the health consequences of eating those foods as part of a good diet so that we don't see competition just around taste and product price and whether it is super-sized or not and whether it springs ready-to-eat out of a box, but also around what it does for your health.

FDA hasn't done as much in the past, I think, as it should to encourage that kind of competition, and we are working with experts from many government agencies on the right way to go about that. We have got a task force right now that includes NIH, the Federal Trade Commission, and we have been in consultation with the USDA experts, as well.

So I think with your leadership on encouraging more of this kind of interaction and more focused effort against these important and urgent public health problems related to obesity and good nutrition, we can make more progress, and I look forward to working with you on that and all the many other issues that no doubt we will have interactions about going forward.

Senator BENNETT. Thank you very much. Again, completely anecdotal, but I am aware of a woman who had very serious obesity problems and she dieted very strictly and she was on the treadmill every day and she continued to gain weight. It was very frustrating to her and she had a number of other problems.

She finally went to a doctor who said, you have got an endocrine imbalance here, prescribed some prescription drugs, and she could eat more than she had been eating before, trying just to cut down on everything and exercise and all the rest of it. She could satisfy her cravings for more nourishment and, in fact, lose weight in the process because there were changes in her metabolism that were stimulated by the prescription drugs that she took. Her husband commented to me, "I am glad to have her back. This is the woman that I married," whereas psychologically and emotionally, the woman he had married had disappeared in the process.

So there is, in addition to all of the things that Under Secretary Bost appropriately said about quit being a couch potato and quit sitting in front of the computer, walk to school instead of ride the bus and so on, there is clear evidence that many of the things you deal with and the things that USDA deals with are interrelated in these complicated mechanisms we call our bodies.

ADDITIONAL COMMITTEE QUESTIONS

The more we can get the Federal Government to spend its research dollars intelligently on this and then communicate intelligently so that ordinary people can say, well, this is the final word, rather than I have to go to the bookstore and rifle through 50 books and hope I find the one book that applies to me, is what I am hoping for eventually.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ROBERT F. BENNETT

ANIMAL DRUG USER FEES

Question. Dr. McClellan, I noted that your budget request assumes the enactment of a new animal drug user fee to expedite the review of applications for animal drugs. As you know, this falls under the jurisdiction of the House and Senate authorizing committees. What is the status of approval of this new user fee?

Answer. You are correct; the first step in making this important FDA program enhancement a reality in fiscal year 2004 is obtaining authorization. The bill, S. 313, "The Animal Drug User Fee Act of 2003" passed by unanimous consent in the Senate on June 3, 2003. A companion bill, H.R. 1260, was introduced with bipartisan support in the House. The measure, as passed by the Senate, requires an appropriations action before FDA has the full legislative authority it needs to collect and spend these fees.

Question. What would be the impact on the center for veterinary medicine if this fee proposal is not enacted?

Answer. Congressional authorization of this user fee proposal to support significant improvements in CVM's new animal drug evaluation process is critical to achieving the Center's initiatives for a sustainable and predictable animal drug review process.

Without the additional resources the user fees are designed to provide, review performance will not improve. Existing delays in review times are already close to exceeding the timeframe within which a new animal drug sponsor can recoup its investment in drug development for most animal drugs. Failure to promote safe and effective new animal drug development may also result in increasing compliance problems associated with illegal drug use, illegal compounding of unapproved animal drugs, use of unapproved chemicals and drugs in food-producing animals, and a resulting increase in tissue residue violations both detected and undetected.

Alternatively, if ADUFA is enacted, the general public as well as industry will benefit from faster animal drug approvals. This will provide greater public health protection by helping ensure that animal drug products that are shown to be safe and effective are readily available; speed public access to new and more cost efficient animal drug products; promote animal health by increasing the availability and diversity of safe and effective drug products that relieve animal pain and suffering without compromising public health; provide the animal health industry significant benefits from earlier marketing of products and more predictable review processes; and, decrease incentives for marketing unapproved animal drug products that have not been shown to be safe and effective through the animal drug approval process.

GENERIC DRUGS

Question. I noted in your budget justification the emphasis you have placed on approving new generic drug applications—$13 million and 40 new staff have been requested for fiscal year 2004. How long does it currently take the FDA to complete the review of a generic drug application?

Answer. During fiscal year 2002, the Office of Generic Drugs approved 295 applications with a median approval time of 18.3 months and an average approval time of 21.4 months. Currently the Agency is reviewing the vast majority, over 80 percent, of applications within 180 days.

Question. Why does it take so long?

Answer. Studies of the FDA processes for new drugs have shown that early communications and guidance can improve drug applications and allow deficiencies to be corrected during the initial review, rather than having to wait for additional re-

view cycles to fix problems. In addition, generic manufacturers have expressed interest in finding ways to improve the quality of their applications, so that more applications can be approved on the first round of review. Therefore, FDA is implementing a new system of early communications with generic drug manufacturers who submit applications. FDA also will provide additional guidance for generic manufacturers preparing and submitting quality, complete applications.

Various interested parties also raise numerous scientific issues when generic products are anticipated. The discussion of these issues is critical as it ensures full consideration of all possible scientific aspects of the product. However, the full examination of these questions can delay the action on generic drug applications. In addition, with the advancement of science, new and more challenging issues are being raised. There are products for which efficient, reliable methods for the demonstration of bioequivalence have not been successfully developed.

Question. What do you plan to do with this funding and staff to shorten that length of time?

Answer. FDA generally can approve generic drugs for the marketplace as soon as the patent protection on brand-name drugs expires or when a court determines that the generic product will not infringe on the innovator's patent or that the patent is invalid. The generics' manufacturers must demonstrate to the FDA that their products are therapeutically equivalent to an approved brand-name drug in terms of safety, strength, quality, purity, performance, intended use and other characteristics.

The proposed increase in the FDA's generics budget will allow FDA to hire 40 experts in its generic drugs program to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. FDA also has begun internal reforms to improve the efficiency of its review process for generic drugs. In particular, FDA is implementing a new system of early communications with generic drug manufacturers who submit applications. FDA also will provide additional guidance for generic manufacturers preparing and submitting quality, complete applications.

Studies of the FDA processes for new drugs indicate that such communications and guidance can improve drug applications and allow deficiencies to be corrected during the initial review, rather than having to wait for additional review cycles to fix problems. In addition, generic manufacturers have expressed interest in finding ways to improve the quality of their applications, so that more applications can be approved on the first round of review.

The new resources and other reforms are expected to reduce the total time to approval for most new generic drugs by 3 months or more over the next 3 to 5 years. Because these changes will generally accelerate the approval for all generic drugs, most Americans who take generic drugs will benefit.

The FDA also will expand its educational programs and partnerships involving generic drugs, to help consumers get accurate information about the availability of generic drugs for their health needs and to help ensure that consumers are aware that FDA-approved generic drugs are as safe and effective as their brand-name counterparts. FDA will also undertake more scientific studies of generic drug "bioequivalence" to expedite the determination of whether the generic copy of a drug works in the same way as the original product, and will enhance monitoring of the safety of generic drugs on the market.

RX TO OVER-THE-COUNTER SWITCHES

Question. During our recent conversation, Dr. McClellan, you mentioned to me your efforts to move more and more medications from requiring a prescription to being available over the counter. One of your reasons, as I recall, was to reduce out-of-pocket costs to consumers by not requiring them to pay for a doctor visit as well as a prescription. This would be especially beneficial to those who do not have health insurance.

There is another side to that coin—the very real danger of self-medicating. There are some products that should not be used in conjunction with others. While these dangers might be listed on the package, many times the print is very small. How do you decide which drugs no longer require a prescription?

Answer. Two of the options available to FDA to switch a drug subject to an approved new drug application from prescription, Rx, to over-the-counter status are voluntary submission and rulemaking.

The simplest, voluntary submission, is when a sponsor voluntarily submits a supplemental NDA to make the switch. The second option, rulemaking, is permitted under section 503(b)(3) of the Federal Food, Drug, and Cosmetic Act. That provision allows the Agency to remove the Rx restriction from a drug such restriction is not

necessary for the protection of the public health. In both instances, FDA must determine that the legal and safety standards for OTC marketing are satisfied prior to allowing the switch. Some factor the Agency considers when determining Rx-to-OTC switch candidates are: an acceptable margin of safety based on prior prescription marketing experience; low misuse and abuse potential; a reasonable therapeutic index of safety; and, self treatment and self monitoring with minimal physician intervention.

Question. Does the manufacturer request this switch?

Answer. Historically, the majority of drugs that have been switched from prescription only to over-the-counter, OTC, status have been at the initiation of the sponsor. However, FDA's regulations allow for any interested party to petition the agency to request to switch a product from prescription to OTC status.

Question. What steps do you take to make sure that these drugs are being used appropriately once they are so widely available?

Answer. Sponsors of approved NDAs are required to file periodic safety reports and these are monitored for adverse events. The Agency also maintains a voluntary reporting system, Medwatch, that is available to all consumers and health care professionals to report adverse events for both prescription and over-the-counter products. In some cases, use studies are conducted prior to switching a drug from prescription to OTC as one way to help ensure that the consumer can appropriately use a product in an OTC setting.

Also, a regulation that will be fully implemented by May 2005 standardizes the labeling format that will improve the labeling on drugs Americans use most, OTC drugs. By clearly showing a drug's ingredients, dose and warnings, the new labeling will make it easier for consumers to understand information about a drug's benefits and risks as well as its proper use.

MEDICAL DEVICE USER FEES

Question. Dr. McClellan, the FDA budget assumes that at least $29,190,000 will become available from the medical device user fees authorized under current law. These funds are to be used to decrease the time necessary for medical device reviews conducted by the Center for Devices and Radiological Health (CDRH). Prior to the enactment of the medical device user fee and modernization act of 2002, how much money was spent for this review responsibility?

Answer. We are currently developing the base line data on how much we spent on the process for the review of medical devices, as recently defined in the Medical Device User Fee and Modernization Act, MDUFMA, in fiscal year 2002—the year before MDUFMA was enacted. We do not have these data yet in large part because the new statutory definition cuts across our traditional accounting categories. The results, when we have them, will be published in the MDUFMA Financial Report that is due to Congress at the end of January 2004.

Question. Of the amounts specifically appropriated to the FDA, not including MDUFMA funds, how much is expected to be spent for this activity in fiscal year 2004?

Answer. Because the new statutory definition cuts across our traditional accounting categories, we do not currently have an accurate estimate on fiscal year 2004 funding. We estimate that it will be at least what was spent on the process in fiscal year 2002, but will have more accurate data when we complete data gathering for the MDUFMA Financial Report.

Question. How many full-time employees were assigned to these reviews prior to the enactment of MDUFMA?

Answer. Approximately 730 FTEs were spent on the process in fiscal year 2002. However, we will have more accurate information when we complete some data gathering that is currently underway. We expect this information to be published in the MDUFMA Financial Report that is due to Congress at the end of January 2004.

Question. Not including MDUFMA funds, how many full-time employees will be assigned to these reviews in fiscal year 2004?

Answer. We anticipate that the agency will assign at least the same amount of FTE on the process in fiscal year 2004 as in fiscal year 2002. However, we will be able to provide better data once we have completed data gathering for the MDUFMA Financial Report.

Question. I noted that of the amount available from MDUFMA, $15,808,000 will be provided to CDRH. Of the remainder, $7,026,000 would be transferred to the Center for Biologics Evaluation and Research, $642,000 would be transferred to the Office of the Commissioner, $2,501,000 would be utilized by the Office of Manage-

ment and Systems, $350,000 would go to the Office of Planning, Policy and Legislation, and a total of $2,863,000 would be applied to rent-related costs.

What contributions are made to the review of medical device applications by each of the entities listed above?

Answer. Device application review is done both in the Center for Devices and Radiological Health, CDRH, and in the Center for Biologics Evaluation and Research, CBER. Most of the review work is done in CDRH, but a significant amount is done in CBER—especially review of diagnostic devices and test kits that incorporate biologics or are used in blood testing work. Resources are allocated between those components in proportion to the amount of device review work that is done by each center, and keeping in mind that all of the appropriated increases, in the devices and radiological health line of the appropriation, are provided to CDRH and the field.

Increases are included in the rent line because additional space will have to be acquired to house the additional staff the agency expects to hire over each year—from an additional 120 FTE in fiscal year 2004 to 265 additional FTE dedicated to this process by 2007.

Increases are also included in funds for the Office of Management and Systems, which collects and manages the fee revenue, hires additional staff, coordinates the acquisition and management of the additional space, provides IT support, and reports to Congress on the financial aspects of the program each year.

The Office of Policy and Planning is responsible for the annual MDUFMA performance report to Congress and for assisting with other management responsibilities for the program, such as the annual stakeholders meetings.

FDA has also allocated funds to the Office of Combination Products, which was mandated by the Medical Device User Fee Act to streamline the processing of complex drug-device, drug-biologic, and device-biologic combination products that play an increasingly significant role in health care.

Question. Before enactment of the medical device user fee authority, how were these responsibilities funded and in what amounts?

Answer. All of the items previously mentioned are related to the implementation of MDUFMA. These activities are over and above any previous resources available to the agency. As a result of MDUFMA, FDA has expanded work related to the review of medical devices by the Center for Devices and Radiological Health as well as the Center for Biologics Evaluation and Research. The additional responsibilities that are being funded by MDUFMA in the Other Activities line of the budget by the Office of Management and Systems, the Office of Policy and Planning, and the Office of Combination Products were not necessary prior to the enactment of MDUFMA. Under MDUFMA, FDA must collect and manage the fee revenue, hire additional staff, coordinate the acquisition and management of the additional space for staff, provide IT support, report to Congress on the financial and performance aspects of the program each year, assist with management responsibilities for the program such as the annual stakeholders meetings, and assist in the streamlining of the processing of complex combination products.

Question. Has there been any reduction in these amounts since the enactment of MDUFMA?

Answer. We will have more accurate information when we complete some data gathering that is currently underway. However, the reductions related to the Devices and Radiological Health program in the fiscal year 2004 request reflect management savings and IT consolidation and should not impact the resources directly devoted to the review process. User fee collections under MDUFMA are not considered an offset for this program. They are used exclusively for the review of new devices and related costs. FDA supports the goals of MDUFMA, and is committed to making the medical device user fee program a success.

DRUG EFFICACY STUDY IMPLEMENTATION MONOGRAPHS

Question. Dr. McClellan, FDA's recent enforcement activity with regard to single entity extended release guaifenesin has focused attention on many prescription products that have apparently been marketed for decades without significant safety or effectiveness concerns, but at the same time are outside of the current FDA drug approval process. I understand that the FDA has given careful consideration to many competing concerns, including upholding the integrity of the new drug approval process, ensuring the availability of affordable medicines, and not unnecessarily disrupting patients and physicians, as well and manufacturers and distributors and the people they employ. Would the FDA consider establishing a monograph system similar to the over-the-counter (OTC) monograph system to deal with these older products?

Answer. FDA believes it would not be feasible to establish a monograph system for certain older prescription drug products. Such a system would have to be developed through notice and comment rulemaking, based on publicly available data, and would be limited to products that have been marketed to a material extent and for a material time and that can be established as generally recognized as safe and effective. It would take many years to develop and implement such a system and would require substantial additional resources. Because of its complexity, we anticipate that developing a monograph system and individual monographs for prescription drugs would be extremely resource intensive and time-consuming.

Furthermore, many prescription drugs are associated with serious toxicity or potential harmful effects and are often for serious indications. Therefore, the types of prescription drugs that would be appropriate for consideration as generally recognized as safe and effective under a monograph system could be very limited. In addition, some categories of drugs would not be appropriate for monographs in any case because they have unique performance characteristics that require review under an application instead of under the general criteria found in monographs. For example, the safety and effectiveness of controlled release dosage forms are highly dependent on the specific formulation, and it would be difficult to ensure the safety and effectiveness of these drugs using a categorical approach such as a monograph system.

Question. Does the FDA have the authority under existing law to establish a monograph system for older prescription products?

Answer. FDA believes that it would be theoretically possible, but infeasible, to establish a monograph system for certain older prescription drug products. Such a system would have to be developed through notice and comment rulemaking, based on publicly available data, and would be limited to products that have been marketed to a material extent and for a material time and that can be established as generally recognized as safe and effective. It would take many years to develop and implement such a system and would require substantial additional resources. Because of its complexity, we anticipate that developing a monograph system and individual monographs for prescription drugs would be extremely resource intensive and time-consuming.

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Question. Under the monograph system for OTC drugs, does the FDA have the authority to take action against products when there are substantial questions regarding safety and efficacy even if the monograph has not been finalized?

Answer. FDA has the authority to take action against an OTC drug subject to a pending monograph when substantial questions regarding safety and efficacy are evidenced. If the drug contains an ingredient that is explicitly prohibited by regulation, 21 CFR 310.545, has label deficiencies that constitute a potential hazard to health, or is adulterated, FDA Compliance Policy Guide 450.200.

GUAIFENESIN

Question. With regard to single entity extended release guaifenesin, I understand that in February of this year, manufacturers and distributors were granted a grace period until November 2003 to obtain new drug approvals for their products. Affected companies obviously would need time to develop the information necessary for a new drug application (NDA) submission.

In light of the fact that FDA's own figures indicate that the median time to approval for standard NDAs has steadied at 12 to 14 months, was that a realistic grace period?

Answer. FDA exercised its enforcement discretion and granted a grace period to prevent undue hardship to the consuming public and the industry that could result from an abrupt cessation of such products' supply. Among other things, this grace period had to be limited in order to preserve the incentives for companies to develop and submit new drug applications, as required by law. The new drug approval process plays an essential role in assuring that all drugs are both safe and effective.

In addition, because FDA had determined that the single-ingredient, extended release guaifenesin drug products were on the market illegally, a decision to leave them on the market indefinitely could have run afoul of the Court's ruling in *Hoffmann-LaRoche* v. *Weinberger,* 425 F.Supp. 890 (D.D.C. 1975).

Finally, single-ingredient, extended release guaifenesin manufacturers actually had much more than the 2 years notice provided to manufacturers of products subject to the cough/cold monograph. The Agency, by regulation, has identified certain drugs as requiring new drug applications for marketing, including all extended release dosage form drug products [21 CFR 310.502(a)(14)]. The Agency's interpretation of that regulation has not changed since it was publicly announced in 1959. It appears that the Warning Letter recipients all began manufacturing their products after that public announcement. When guaifenesin was considered for OTC marketing by the Agency in rulemaking proceedings, the Agency repeatedly reaffirmed, in the Federal Register, the existence of the longstanding Agency policy requiring new drug application approval prior to marketing extended release drug products. FDA Compliance Policy Guide section 440.100 (CPG 7132c.02) has also clearly stated for many years that any drug on the market without FDA approval is subject to regulatory action "if it is identical or related to a post-1962 NDA approved for safety and effectiveness." Thus, the manufacturers of single ingredient extended release guaifenesin products had ample notice that they faced immediate removal from the market.

Question. I note that on December 23 of last year, the FDA finalized the OTC monograph for cough and cold products with more than one active ingredient, so-called "combination cough/cold products." Manufacturers and distributors are not required to come into full compliance with the monograph until December 2004. Why were these OTC products given 2 years to conform to the monograph or come off the market when single entry extended release guaifenesin prescribed by physicians has to come off the market at the end of a 9-month grace period?

Answer. The final monograph for cough/cold combination drug products that issued in December 2002, was developed under the OTC Drug Review process. The monograph set forth the criteria for such drugs to be generally recognized as safe and effective, i.e. not unapproved new drugs. The rulemaking process, established in 1972, provided that OTC drug products would not be deemed to be unapproved new drugs until after the effective date of the final monograph. In other words, the OTC Review process itself provided for a period of time during which a firm could bring its product into compliance with a final monograph and permitted continued marketing during such time period. In the case of the cough/cold drug products, the 2-year time period was determined to be reasonable and necessary to enable affected drug manufacturers to reformulate and print new labels to comply with the final rule.

The recent action taken by FDA with regard to single-ingredient, extended release guaifenesin drug products involved the issuance of Warning Letters in October 2002 to manufacturers and distributors of such drug products, advising those firms that their drugs were unapproved new drugs. In that case, FDA exercised its enforcement discretion and granted a grace period to prevent undue hardship to the consuming public and the industry that could result from an abrupt cessation of such products' supply. Among other things, this grace period had to be limited in order to preserve the incentives for companies to develop and submit new drug applications, as required by law. The new drug approval process plays an essential role in assuring that all drugs are both safe and effective. In addition, because FDA had determined that the single-ingredient, extended release guaifenesin drug products were on the market illegally, a decision to leave them on the market indefinitely could have run afoul of the Court's ruling in *Hoffmann-LaRoche* v. *Weinberger,* 425 F.Supp. 890 (D.D.C. 1975).

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safety and effectiveness." Thus, the manufacturers of single ingredient extended release guaifenesin products had ample notice that they faced immediate removal from the market.

DIETARY SUPPLEMENTS

Question. Dietary supplements are products that are regulated as a food product. These are products made from herbs or certain ingredients and these products are not permitted to make claims that they "cure diseases." Rather, they are permitted to make "structure and function" claims, as long as there is scientific information supporting these claims.

The law is clear. If there is a safety concern about a product and the product causes a substantial risk of harm, then FDA may withdraw the product from the marketplace. However, if the scientific evidence is not clear, the Dietary Supplement law permits the agency to take other actions.

The FDA is the administrative body that we have authorized to make sound scientific judgments within, let me repeat, within the parameters of the law.

Let's talk about what has occurred to date. Dr. McClellan I understand that you have taken very swift action on the issue of ephedra and have proposed rules to require very strong warning labels on dietary supplement products that contain ephedra. In addition, I understand you propose that these products not be used by children or by athletes as an athletic performance enhancer.

Dr. McClellan, I also understand that you have reviewed various scientific studies, including one commissioned by the FDA that looked at the adverse event reports. It is my understanding that the Rand Institute, an independent think tank, conducted a study and reviewed these reports on ephedra leading up to this regulatory process. They stopped short of saying that ephedra caused the adverse events.

Do you intend to finalize these rules in the near future? Will you commission additional studies on this matter or do you feel you are getting additional information through rulemaking?

I believe that the Agency is taking the correct approach: they are evaluating the law; they are looking at the scientific evidence; they are taking strong administrative action; and I believe that it is consistent with their mission in overseeing products under their authority.

Answer. The agency remains very much concerned about the safety of dietary supplements containing ephedrine alkaloids. The agency is currently examining all comments to its March Federal Register notice. Upon consideration of all the comments, the agency will take the most appropriate action consistent with the law to best protect public health. The actions may or may not necessitate rulemaking. If the agency issues a rule, it may include labeling, as well as marketing restrictions. We do not anticipate commissioning any further studies at this time.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

DIETARY SUPPLEMENTS

Question. The FDA has the primary role in regulating as well as assuring the safety of dietary supplements, like Ephedra. Scientific data are critical for developing policies regarding dietary supplements and for demonstrating safety. I understand that a number of scientific studies have yielded questionable results due to a lack of quality of the supplements being tested. Would a source of standardized products improve the scientific testing of these products as well as the safety of these products for consumers?

Answer. Scientific data establishing the botanical and chemical profiles of authenticated botanical ingredients, such as ephedra, provide the essential basis for developing standards that can be used in a variety of ways to enhance scientific research and regulatory decisions. Such standards can provide a basis for evaluating Good Manufacturing Practices, GMP, in order to confirm that the ingredient used in a product is the ingredient intended for use. Adulterations or mis-identifications can more easily become apparent. This use has value for FDA in enforcement actions, for industry in establishing and monitoring GMP provisions, and for researchers in characterizing the test substance used in their own studies and for comparing results across studies performed by different laboratories.

Validated analytical methods for detecting contaminants in botanical and other dietary supplement ingredients are valuable to regulators, researchers, and manufacturers. If such methods were widely available, they would help ensure that supplement ingredients do not contain unsafe levels of contaminants such as heavy metals, pesticides, and drugs.

Sound scientific information on the botanical and chemical profiles of authenticated botanical ingredients and validated analytical methods for contaminants and adulterants would help assure the standardization of test products for research and the purity of marketed products.

NATIONAL CENTER FOR NATURAL PRODUCTS RESEARCH

Question. I have followed with interest the collaboration between the FDA's Center for Food Safety and Applied Nutrition, and the National Center for Natural Products Research at the University of Mississippi. The FDA has indicated it has plans to expand this relationship. Can you comment on the value of this collaboration? Does the Center for Drug Evaluation and Research also plan to undertake similar collaborations in order to deal with dietary supplements that may be submitted for approval as drug products?

Answer. Under the Dietary Supplement Health and Education Act of 1994, DSHEA, FDA has primary responsibility for ensuring that appropriate regulatory actions are taken against marketed dietary supplement products that present significant health risks or bear false or misleading label claims. Policy decisions that require the evaluation of risks and claims need to have a sound scientific base. For botanical dietary supplements, development of such a science base is especially problematic because of several unique features, including the complexity of the constituents, variability of sourcing, lack of availability of reference materials, lack of manufacturing controls, and new and rapidly expanding uses in the marketplace. The existing cooperative agreement between the University of Mississippi, National Center for Natural Products Research, NCNPR, and FDA was established to address these critical research issues.

In September 2001, FDA implemented a cooperative agreement with the National Center for Natural Products Research, NCNPR. This agreement was amended in September 2002, to increase overall funding of the project. The agreement between FDA and NCNPR creates a partnership that allows for more efficient use of resources to identify and analyze specific components in botanical dietary ingredients, thereby enhancing overall public health by ensuring that dietary supplements are safe and their labeling is not misleading.

Accomplishments to date have included collection and chemical profiling of a number of botanicals, e.g., a variety of ephedra species, aristolochia and asarum species. Scientific workshops have either been held such as the "Authentication of Botanicals" in August 2002, or are planned—such as "Use of Hepatoxicity Methods to Evaluate Safety of Botanicals" in September 2003. In addition, collaborations have occurred between NCNPR staff and FDA's National Center for Toxicological Research, with the methods validation project co-funded by FDA and NIH with the Association of Official Analytical Chemists, AOAC, with NIH's Office of Dietary Supplements, NIH/ODS and their Clinical Research Program for Dietary Supplements, and with the National Toxicology Program NIEHS/NIH-sponsored research in botanical safety.

Future plans include the continuation of the basic efforts on collection and chemical profiling of authenticated botanical materials noted above with the inclusion of additional botanicals as current efforts are completed, holding additional scientific conferences and workshops, and continuation of collaborations between individual scientists at FDA's Center for Food Safety and Applied Nutrition, CFSAN, and NCNPR including the sharing of samples and research data. This expansion will greatly enhance the already useful chemical profiling information that FDA is receiving from the NCNPR/University of Mississippi collaborative agreement in that it will provide a more complete body of evidence on which to evaluate safety. Activities carried out under the Cooperative Agreement contribute significantly to the Center's dietary supplement program and expand the capabilities of researchers at both Centers.

A dietary supplement submitted for approval as a drug product and intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease would undergo our new drug application, NDA, review process. We would seek expert advice through Advisory Committees when necessary.

CITIZENS' PETITION—CFC GAS AND ASTHMA PRODUCTS

Question. Please provide us the status, within the FDA, of the citizens' petition that calls for the removal of certain asthma products, called metered-dose inhalers, from the list of essential uses for CFC gas.

Answer. The American Lung Association's, ALA, citizen petition requesting the elimination of the essential use designation for albuterol presents serious and complex policy issues.

Section 2.125(f) specifies the 4 criteria for determining that a use of an ozone-depleting substance is no longer essential. A citizen petition must present "compelling evidence" that all criteria are met. The second criterion is that "supplies and production capacity for the non-ODS product's exist or will exist at levels sufficient to meet patient need." ALA states that information that will support their desired finding on this criterion is proprietary, but it can be developed in the course of rulemaking. We have not received any comments providing information on supplies and production capacity of alternatives.

RX TO OVER-THE-COUNTER SWITCHES

Question. As you point out in your statement, nonprescription drugs are becoming more important in our health care system as more products switch from prescription to over-the-counter status. The Administration has requested an additional $1 million to "improve the OTC drug review process" through hiring and training personnel. In your opinion, what impact do these products have on the health of Americans? Will the additional funds be used to complete the switch applications that are currently pending or initiate new switches?

Answer. Over-the-counter, OTC, drugs play an increasingly vital role in America's health care system. With reports of rapidly increasing spending on prescription drugs, interest in finding ways to curb those costs is also intensifying. The trend to patient directed-medication has increased greatly in recent years as health care costs have risen and consumers want to be empowered to treat minor ailments with safe and effective OTC drug products. The mission of OTC drug review at FDA is to protect and promote the health of Americans by providing access to important safe and effective OTC drug products.

The requested increase in funding will be used to hire and train seven additional FTEs to improve the OTC drug review process, develop and work toward finalizing OTC drug monographs, and conduct consumer behavior research that would be used to identify and manage potential risks of OTC drugs. Additional staff will assist in expediting all processes within the review division, making available OTC products in a timely manner.

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER S. BOND

MEDICAL DEVICE USER FEES

Question. Dr. McClellan, you're to be congratulated for your role in reaching a deal with the medical device industry that requires them to pay $150 million in user fees over the next 5 years. This deal also requires the government to match industry funds with a relatively modest $45 million increase to be attained over the years 2003–05. I'm disappointed that the Administration's budget for fiscal year 2004 fails to provide the funds required under this agreement in fiscal year 2004. Yet, you've proposed new increases in other areas of FDA activity. Can you assure me that, notwithstanding your proposed new initiatives in non-device areas, you will meet your obligations under the device user fee agreement?

Answer. FDA assures you that it looks forward to working with Congress and industry to ensure the device user fee program is successful. FDA is committed to meeting the performance goals, as stated in the goals letter. We have already begun discussions within the Administration to find ways to fund this program appropriately in fiscal year 2005 and beyond to ensure that this important program does not sunset.

Question. The user fee agreement only requires you to meet current performance for the first 3 years of the program, even as you collect fees from industry. Yet I understand the agency's position is that you can't meet these modest goals without the additional funds that are to come from appropriations.

With the $15 million increase we appropriated to CDRH for fiscal year 2003 plus the $27 million in user fees industry will pay, the CDRH budget is substantially larger in fiscal year 2003 than it was in the previous fiscal year. I've noticed that you propose a number of management efficiencies at the agency. In addition, you announced new initiatives to help speed multi-cycle reviews of promising new medical technologies through FDA. Why can't you meet the modest performance goals required by the device user fee agreement using these efficiencies combined with the increased funds that Congress and the device industry are already giving you?

Answer. The appropriations for devices and radiological health in fiscal year 2003 provided an increase of $12.5 million over the fiscal year 2002 appropriation. Of this amount, $5.2 million was to fund the costs of the Federal pay increase for existing employees, $3.4 million was to enhance the counterterrorism capabilities of FDA's

field operations. The increase of $1.5 million and 1 FTE for patient safety/medical errors and the additional $4.0 million added by Congress gave us some additional device review capabilities—as will the management efficiencies that we expect to achieve in fiscal year 2004. These amounts were offset by the $1.7 million rescission of 0.65 percent.

We fully expect to meet the only performance goal that applies for fiscal year 2003 and fiscal year 2004—complete action on 90 percent of the amendments containing complete responses to an "approvable" within 30 days. The more challenging MDUFMA goals take effect in fiscal year 2005, and become increasingly more challenging each subsequent year through fiscal year 2007. We allowed more time before these goals take effect because we will have to hire and train additional staff to be able to meet these goals.

Question. Passage of the device user fee agreement was the culmination of a 10-year effort to win over the strong resistance to user fees of many in the device sector and in Congress. I understand that if FDA does not receive a $45 million increase for the device program by fiscal year 2005, the user fee agreement terminates and the agency loses the ability to collect fees from industry in the remaining 2 years of the program. Given the history of the user fee issue in the device sector, I suspect you'll lose this program and any chance of collecting fees from the industry again if you don't find a way to meet the performance goals. What is your plan to avoid losing this program and this funding source that I suspect you need and want?

Answer. The agency looks forward to working with Congress and industry to ensure the device user fee program is successful. FDA is committed to meeting the performance goals, as stated in the goals letter. We have already begun discussions within the Administration to find ways to fund this program appropriately in fiscal year 2005 and beyond to ensure that this important program does not sunset.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

BOVINE SPONGIFORM ENCEPHALOPATHY

Question. Dr. McClellan, as you know, in the 1990s, during the BSE crisis in Britain, millions of cattle were slaughtered and burned, and significant amounts of feed were removed from the market. In 1997, FDA banned the use of certain contents in animal feed in order to try and stop the spread of BSE. What has FDA done to make sure that none of the feed removed from the market in Europe, or any of the remains of the destroyed cattle, have entered the United States on the black market in our animal feed?

Answer. FDA has prioritized the review of our import entries to make sure that all of the possible commodities that might be or contain the mammalian proteins prohibited from use in ruminant feed are reviewed before entry into the United States. In addition, we have an Import Alert in place which instructs the FDA import personnel to detain without physical examination any product that is or contains any animal protein product from the countries identified by USDA/APHIS as "restricted" either because they have identified a case of BSE in that country or they are at risk for BSE because they have open commerce with those countries. That includes all of the European countries, Japan, and Israel, as well as Canada.

We also have an ongoing assignment to collect samples and analyze animal feed products using feed microscopy from the BSE positive or suspect countries in which the documents indicate no processed animal protein is present to be assured that products are not being entered through intentional or inadvertent mislabeling. To date none of these samples have found the presence of processed animal protein.

On an ongoing basis, FDA meets with USDA and Customs to coordinate the U.S. review and response to products offered for entry into the United States.

Question. How is the FDA involved in the investigation of the Canadian case, especially in regard to tracing the feed that this herd consumed?

Answer. FDA is working cooperatively with Canada in the investigation of this incident. Technical counterparts are communicating on a regular basis as the investigation unfolds. A representative from FDA's Center for Veterinary Medicine spent a week in Canada working with CFIA officials. FDA was notified by CFIA about pet foods that were potentially contaminated with rendered material from the BSE positive cow in Canada and shipped to the United States. The firm has asked for return of all suspect products and FDA has issued notices to alert consumers about this information. FDA is currently part of a daily interagency conference call that shares information on the investigation of this incident. The call includes representatives from USDA/FSIS and APHIS, as well as CDC. Each of those agencies is working with their respective Canadian counterparts.

REGULATION OF ANIMAL FEED

Question. Please explain specifically how FDA regulates animal feed. Specifically, are there inspectors in all plants? Is there testing at the borders? How does FDA actually enforce its feeding ban?

Answer. FDA regulates animal feed through the administration of the Federal Food, Drug, and Cosmetic Act, the Act. Animal feed is food under the Act. In general, food must be truthfully labeled and may not be adulterated. The Act, among other things, prohibits the interstate shipment of adulterated or misbranded food, and the adulteration or misbranding of food after receipt in interstate commerce. What constitutes adulteration or misbranding is defined in the Act. Food additives must be shown to be safe prior to their use in food. In addition, drugs are often administered to animals through feed and therefore, many animal feeds contain drug products and are called medicated feeds. The drugs go through a pre-approval process, and the medicated feeds must be manufactured in conformance with Current Good Manufacturing Practices regulations to assure appropriate controls are in place for the manufacture, processing, and distribution of the medicated feeds. Generally, feed mills that use potent drugs that require pre-slaughter withdrawal must be licensed by FDA to receive and manufacture feed containing those drugs.

The regulation of animal feed, as with most FDA regulated commodities, begins with inspection of the manufacturing and distributing operations for feed and feed ingredients. The inspections are physical and include discussion with management and employees; plant walk through and observation of the processing; examination of equipment, plant premises, and grounds; and, review of records. Inspections are generally conducted biennially if certain potent drugs are used, and on an as needed basis for other firms. FDA is not in the plant at all times. However, we may conduct inspections multiple times during the year if there is a need; for example, to follow-up on an inspection that found violations of the law, to confirm that commitments to compliance were implemented, or when new information arises that indicates a possible violation of the law. We also work cooperatively with our state counterparts who may also be conducting inspections of a plant at various times throughout the year. We may also collect samples for analysis during the inspection or at sales or use locations.

FDA is notified of shipments of imported products. We may review the incoming documents for the shipment, physically examine the shipment, and collect samples for analysis. Products that are not acceptable for distribution in the United States are refused entry. In some circumstances, the owner may be able to recondition the product so that it would be acceptable such as by making labeling changes where the basis for refusal is improper labeling. FDA would monitor the reconditioning and examine the shipment before permitting entry.

Under the BSE feed ban, certain mammalian proteins are deemed food additives when used in ruminant feed; these are referred to as prohibited material. They have not been shown safe for use in those feeds and are therefore not permitted. Any ruminant feed containing these proteins would be adulterated. For non-ruminant feeds that do contain these proteins, the feed ban requires measures to prevent commingling and cross contamination, record keeping, and caution statement labeling.

FDA has taken a multipronged approach to enforcement of the feed ban. FDA, in conjunction with the states and trade associations, has done extensive education of the regulated industries. We also conduct 100 percent inspections of all renderers, protein blenders, and feed mills, as well as a percentage of other firms such as distributors and ruminant feeders. We have pursued enforcement action for firms that have failed to bring their operation into compliance. As of May 2, 2003, 59 Warning Letters have been issued, and 42 firms have recalled over 241 products. The Act provides additional enforcement tools including seizure of violative product, injunction, and prosecution. Currently, we are conducting inspections of all firms that handle prohibited material annually. We also give priority for inspection to any firm that was found out of compliance on the previous inspection and any firm that we have information indicating possible violations are occurring.

Additional enforcement activities include the development of a new BSE Compliance Program with input from a wide range of FDA and state officials, and two national meetings to introduce the Program. The purpose of the Program is to provide complete instructions to FDA and State investigators in conducting domestic BSE inspections and evaluating imported animal feed products from BSE-at-risk countries. FDA has also worked with a contractor to incorporate the BSE feed ban inspection information into the FDA FACTS System providing increased data integrity, increased ability to obtain information on the inspection obligations and their status, and enhanced ability to monitor compliance activities. Part of this database enhancement included a new BSE inspection checklist to improve data reporting for

inspection. We have also trained field employees in the use of this new checklist and on the present BSE regulatory strategy. FDA also initiated training and installation of the Harvard BSE Risk Assessment simulation to enable FDA to test proposed risk management strategies in terms of the effects on the spread and the rate of disappearance of BSE should BSE be accidentally introduced into the country. In addition, FDA conducted a series of interagency tests of the FDA BSE Response Plan, and a satellite-training course on the BSE Contingency Plan. FDA revised the BSE Response Plan and published it on FDA's web site. FDA presented a national satellite broadcast, entitled "BSE Import Safety Net", to FDA, U.S. Customs Service and USDA inspection and compliance personnel. FDA is still physically collecting and analyzing import samples from known BSE countries identified as at-risk for BSE, for the presence of mammalian protein; no processed protein should be coming in from at-risk countries. This assignment to date has not found any violations.

ADMINISTRATIVE SAVINGS

Question. FDA's fiscal year 2004 budget request is approximately $24.5 million above the fiscal year 2003 appropriated level, not including user fees. When looking at the budget, I was pleased to see that the request includes increases for food safety, patient safety, over-the-counter and generic drugs, and other increases totaling approximately $79.5 million. However, in order to pay for these increases, the budget proposes cuts of approximately $58 million. The explanations for these cuts in the budget is very brief, and I would like more information on them. The budget includes a cut of $28 million for "management savings", and states that it will be accomplished by, and I quote, "reallocating resources, realigning and reorganizing functions." What specifically does this mean, and how was this savings amount formulated? What effect will this have on FDA employees?

Answer. FDA is supporting various administration and department initiatives associated with the President's Management Agenda by consolidating human and IT resources to achieve greater efficiencies and economies of scale; consolidating the biologic therapeutic review function into the similar drug review function to achieve greater consistency and less duplication of effort, conducting outsourcing studies and rightsizing to achieve cost savings and maximum efficiencies; organizational delayering for faster decision-making and better communications; and, implementing a new financial management system to provide agency managers with timely and consistent financial information.

Organizational de-layering to achieve a flat, streamlined Agency where decision-making and better communications exists is being aggressively pursued. FDA is also consolidating its administrative functions into a Shared Services Organization, SSO. The SSO concept will allow FDA to provide administrative support functions to Agency components to meet critical mission needs in the most efficient and effective manner possible. These efforts will place the Agency in a position to more effectively and efficiently meet the challenges of providing better protection to consumers and promoting better health.

As a result of the planned efficiencies expected from the migrating to shared services and results of our competitive sourcing initiatives, we expect to realize the savings as depicted in the budget.

Question. The budget also states that IT infrastructure functions are being consolidated, and the budget supports DHHS efforts to "improve the HHS Information Technology Enterprise Structure." These activities are resulting in a $29.5 million cut in FDA's budget. How was this savings amount formulated, and how much of it is actually showing up in the Department's fiscal year 2004 budget? Specifically, what is not being done or funded in order to come up with this money? Will we be seeing further "IT savings" in order to improve the DHHS IT system?

Answer. IT consolidations will result in improved processes that will ensure that the Agency commits to the right projects for the right cost. FDA's budget request includes savings of $29.6 million in the IT budget from both ongoing infrastructure consolidation efforts as well as reduced expenditures through the consolidation, streamlining, postponement or elimination of specific lower priority projects.

The Agency will fully implement its IT infrastructure consolidation by October 2003, thereby reducing infrastructure expenditures in fiscal year 2004 by $15.0 million. These reductions will be achieved, in part, by the ability of the Agency's Chief Information Officer, CIO, to exercise better control over IT decision making, including the identification of inefficiencies as targets for reduction. The CIO will also look for opportunities that, based on a sound business approach using a rigorous cost-benefit analysis, would benefit from the integration of new technology. As a further by-product of consolidation, the Agency will also foster standardization of management processes, thereby increasing the effectiveness of IT even as FDA reduces

overall costs. These improved processes will ensure that the Agency commits to the right projects for the right cost.

Additionally, FDA will reduce spending on development of specific IT systems across the entire Agency by $14.6 million. Managers of information technology organizations allocated reductions to the development of IT systems based upon one of three rationales for increased efficiencies. First, consolidation of similar systems either within FDA or the Department will provide savings in the cost of contracts and government personnel while reducing unnecessary duplication. Second, streamlining work processes and underlying IT processes will provide additional savings. Some of the improvements to IT processes will include better project management, more reliable tools to estimate costs and schedules for use in improved contract performance management, and consistent development practices. Third, lower priority projects will be scaled back or eliminated where reasonable to do so. The impact of reducing efforts on lower priority projects will be mitigated by improvement in work processes achieved through consolidation and streamlining efforts.

MEDICAL DEVICE USER FEES

Question. Dr. McClellan, as you're aware, last year the Congress passed the Medical Device User Fee and Modernization Act, which requires the medical device industry to pay a portion of the cost for FDA to approve their products. Although I am not on the authorizing committee that put this bill together, I understand that there are requirements for certain levels of appropriated funding, and if this funding isn't provided, the program sunsets after 5 years. I also understand that FDA was consulted regularly when this bill was being developed—and was supportive of it. However, I don't see any increase in FDA's budget to help meet these appropriations targets. Further, I have been told that FDA now needs an increase of $22 million in appropriated funds this year, strictly for medical device review activities, in order to meet its targets set by law. Why did FDA agree to these appropriations targets if it had no intention of requesting funding to meet them?

Answer. The Administration has to balance the many competing demands of each component within the Federal government with the total resources available. As a result, the fiscal year 2004 President's budget request for the Food and Drug Administration fell below the levels specified in MDUFMA. We support the goals of MDUFMA, and are committed to making the medical device user fee program a success.

Question. If Congress provides FDA with the President's budget request this year, please explain what effect that will have on the implementation of MDUFMA—will FDA still be able to meet its performance goals for this year?

Answer. The agency is committed to meeting the MDUFMA goals to the maximum extent possible with the resources that are available. We want the program to be as successful as the prescription drug user fee program. We fully expect to meet the performance goals that apply for fiscal year 2003 and fiscal year 2004—complete action on 90 percent of the amendments containing complete responses to an "approvable" within 30 days. The more challenging MDUFMA goals do not take effect until fiscal year 2005, and become increasingly more challenging each subsequent year through fiscal year 2007. We have allowed more time before these goals take effect because we will have to hire and train additional staff to be able to meet these goals.

Question. Does FDA plan to request the necessary funding in the future to meet the MDUFMA appropriations requirements in order to both help FDA meet its performance goals, and to prevent the program from expiring?

Answer. The agency looks forward to working with Congress and industry to ensure the device user fee program is successful. FDA is committed to meeting the performance goals, as stated in the goals letter. Agency leadership has already begun discussions within the Administration to find ways to fund this program to ensure its success.

Question. The President's fiscal year 2004 CDRH appropriations request is $185 million, is a decrease of $9 million from the fiscal year 2003 appropriated level of $193 million. At the same time, CDRH is proposing to collect $16 million in collecting user fees in fiscal year 2004. One could assume from these facts alone that these user fees, which were meant to be additive in nature, and not to replace appropriated funds, are doing just that. Please explain.

Answer. One of the provisions of MDUFMA requires that the funds from fees must be in addition to an appropriation amount that is as great as the amount FDA spent on the device review process from appropriations in fiscal year 2002—the year before MDUFMA went into effect—adjusted for inflation. This provision is meant to assure that appropriated resources available for device review are increased for in-

flation each year, and that the funding from fees is over and above a set level of appropriations, after adjustment for inflation. We are committed to working with Congress and the Administration to ensure that this intent of MDUFMA is realized. The reductions for the Device and Radiological Health program reflect management savings and IT consolidation, as discussed previously, and should not impact the resources directly devoted to the review process.

SEVERE ACUTE RESPIRATORY SYNDROME

Question. We have all been reading the news stories and following the development of SARS. So far, we in this country have been very lucky, but just this week Secretary Thompson said that he believes we will see SARS deaths here. Hopefully, though, the efforts of the FDA, CDC, and other governmental and private entities will make us as prepared as we can be in the event of an outbreak in the United States. I read the statement that Dr. Lumpkin, the FDA Principal Associate Commissioner, gave to a House Committee a few weeks ago, outlining several steps FDA is taking in regard to SARS. This included working to identify the virus, working on drugs to treat and vaccines to prevent the virus, ensuring there are enough medical products available to deal with SARS, and protecting our blood supply. Often, when emergencies such as this arise, there is a need for supplemental funding beyond what is in the budget. Please briefly describe for us the activities FDA is undertaking in regard to SARS. Is there, or do you anticipate a need for additional funding to help fully fund all of FDA's SARS-related activities?

Answer. FDA is carefully tracking the scientific progress in defining, treating and, ultimately, defeating SARS to ensure that all FDA resources are aggressively and effectively deployed in the battle against this new virus.

FDA's Center for Biologics Evaluation and Research—CBER—is working with other government agencies and the private sector to address many of the most difficult early issues in vaccine development. As this program is in its infancy, much painstaking work must be accomplished to assure that the development and manufacturing processes meet the standards required to produce safe and effective vaccines

On April 17, 2003, FDA issued guidance to the Nation's blood establishments on measures for further safeguarding the blood supply against SARS including recommendations for deferral of certain donors. FDA took this interim measure to assure the safety of the blood supply while more is learned about the disease. At this time, it is unknown whether SARS can be transmitted through blood. If tests are developed that can detect SARS in blood, adaptation of those tests to screen blood donations is likely and would be helpful. FDA will work with manufacturers to facilitate the development of those tests. In addition, manufacturers of products made from blood, for example plasma-derived therapeutics, may need to evaluate their need for viral inactivation methods to be sure that their processes are capable of removing the virus. FDA will work with these manufactures to validate and implement any new necessary processes as rapidly as possible.

FDA will continue to monitor this evolving situation and intends to make any revisions or additions as needed to preserve the safety and availability of the blood supply, based on the best available information. For example, FDA's guidance may be modified based on further scientific research on whether the causal agent of SARS may be present in the blood of persons subject to this interim deferral. As in any deferral decision, the need to evaluate the effect on supply also must be considered.

FDA's Center for Devices and Radiological Health—CDRH—is working with CDC, who along with others in the SARS Laboratory Network organized by World Health Organization—WHO—is helping further the scientific understanding of the virus. A diagnostic test for SARS, based on the detection of RNA sequences in the novel coronavirus, is currently under development along with an enzyme-linked immunosorbent assay—ELISA—test for antibodies to the SARS-related virus. The first of these tests, using polymerase chain reaction—PCR—technology, will help with acute diagnoses of patients, while the ELISA test will be used to confirm a case during or after convalescence. CDC developed these prototype experimental reagents over the past 2 months in an effort to address this unmet public health need. FDA rapidly reviewed information for the investigational use of this test, and is working closely with CDC to develop appropriate information for patients and health professionals, and an approach for further evaluation of this new test. This test methodology will be distributed to approximately 100 specialized laboratories around the country. Under the terms of this test's wider distribution, patients and practitioners will receive clear information about the test when it is used to assist

in diagnosing SARS. Hopefully, this information will facilitate the development and evaluation of an approved diagnostic test as quickly as possible.

CDRH is reaching out to industry to ensure that any development plans for new tests are well designed and that premarketing applications submitted to the Agency are of such quality that a priority review can swiftly proceed. In addition, FDA has already cleared or approved dozens of tests for use in differential diagnosis of acute respiratory syndromes and has put in place a postmarket surveillance program to measure how well these tests are working. These tests do not diagnose SARS; rather they help to diagnose other conditions that may have symptoms similar to SARS. In this way SARS can be ruled out as the diagnosis in these patients. CDRH is also monitoring the Internet to see if products are being sold with false claims of detecting the SARS virus. If such products are found FDA will take action to protect consumers from being harmed by them.

FDA's Center for Drug Evaluation and Research—CDER—is currently working with the private sector and other governmental agencies to identify drugs that may have utility in the treatment of SARS. CDER has contacted pharmaceutical companies in order to help identify candidate drugs with potential utility for the treatment of SARS. CDER has also helped to facilitate communications between companies and other governmental agencies—NIH and the U.S. Army Medical Research Institute for Infectious Diseases, USAMARID—involved with the preliminary evaluation of these drugs in screening tests. Sixteen drugs from nine companies were identified as candidate drugs for preliminary testing to evaluate whether the compounds have activity in vitro against the SARS coronavirus.

CDER has worked closely with CDC on the development of an investigational protocol for the treatment of patients with SARS. This protocol provides a mechanism for patients with suspected SARS that meet certain medical criteria to be treated with intravenous ribavarin—an investigational antiviral drug not otherwise available. The study provides a means for patients to receive intravenous ribavarin, an agent that may have therapeutic utility for SARS.

CDER is working with NIH and CDC regarding the possible development of a controlled clinical trial to critically evaluate the utility of therapeutic agents for the treatment of SARS. Similar to CDER's interactions to interactions with the CDC on CDC's protocol, CDER has been in contact with members of the Collaborative Antiviral Study Group and NIH in order to facilitate and expedite the review of any protocol under development for the treatment of SARS.

CDER is involved in ongoing monitoring of the supplies of the drug ribavarin, which is available in several formulations. This work allows CDER to keep abreast of the current levels of ribavarin supplies in order to be able to forecast how much drug may be available to meet potential future clinical needs.

SARS was first detected after the budget was submitted to Congress, and as a result, was not addressed in the request.

Question. Has funding been diverted from other activities because of the SARS effort? If so, which activities?

Answer. In fiscal year 2003, the Center for Biologics Evaluation and Research, CBER, is redirecting an estimated $1.3 million of its resources to SARS-related activities. Many of the CBER staff who currently perform regulatory policy, review and research are the same staff who also focus on other areas such as West Nile virus, and counterterrorism.

In fiscal year 2003, the Center for Devices and Radiological Health, CDRH, is redirecting an estimated $200,000 of their resources to SARS-related activities. CDRH redirected some of their efforts away from routine premarket application review to address SARS-related concerns and applications.

The Center for Drug Evaluation and Research, CDER, has not diverted any funds from other activities for SARS efforts since this is part of the CDER's Emergency Preparedness readiness efforts. The Center will continue to promote and protect public health by assuring that safe and effective drugs, including all SARS-related drug products, are available.

BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Question. The Bioterrorism Preparedness and Response Act of 2002, the Bioterrorism Act, required FDA to implement several changes to strengthen its' food safety regulations, including the development of a system to register products manufactured abroad, by December 12 of this year. Four major proposed rules have been published since January, and I understand that approximately $12 million from fiscal year 2002 supplemental funding has already been spent on the registration system. Further, the budget requests an increase of $20.5 million for food safety, in part to fund the implementation of the new food safety requirements and registra-

tion system. Specifically, what has the $12 million in funding been spent for, and what remains to be done on the registration system?

Answer. FDA has allocated approximately $12.3 million from base resources for the registration and prior notice systems in fiscal year 2003. Approximately $4.3 million of this funding is from the fiscal year 2002 counterterrorism supplemental. Funds for the registration system include hardware, software, and contractor services for the design, development, testing, and implementation of the web-based electronic registration system. The registration system funding also includes funding for office space, hardware, software, and contractor services for the design, development, and initial staffing for the paper registration process, as well as the Help Desk for electronic and paper registration. The Help Desk will also handle calls about use of the prior notice electronic system also required by the Bioterrorism Act.

The electronic registration system is currently being developed and tested. A prototype has been successfully demonstrated to food industry and foreign embassy representatives at four public meetings. The project is on time, and the goal is to have the electronic registration system operational by October 12, 2003 allowing 2 months for facilities to register before the December 12, 2003 deadline. The paper registration process has been designed. The design of the Help Desk and the implementation of the paper process are in the final stages of contract award. The Help Desk implementation will be awarded once the design is completed.

The prior notice system has been allocated funds for infrastructure design, procurement, setup, operations and maintenance of computer system hardware, system/database software and licensing, and contractor services for the design, development, testing, and implementation of the web-based electronic prior notice system. Funding will also be utilized for extensive enhancements required to the Operational and Administrative System for Import Support, OASIS, system to support prior notice.

The Bureau of Customs and Border Protection, CBP, is cooperating with FDA to permit current filers to use the existing Automated Commercial System, ACS, software to submit prior notice. FDA will develop and maintain two separate interfaces. The first expands the current Automated Commercial System—OASIS interface to incorporate the requirements for prior notice. The second is the web interface to capture prior notice for types of entries that have traditionally been exempt from Customs entry—i.e. mail, low dollar value entries, etc.

FDA is integrating the prior notice requirements into the OASIS import entry processing system and making modifications to FDA's OASIS and Automated Commercial System interface. Additional modifications to the data warehouse decision support system will support the matching, standardization and validation of registration and prior notice information, ensuring high quality, consistent data. Enhancements to the automated import screening process to validate registration and prior notice will support inputs from both the web-based system and ACS. The existing entry review process in OASIS will be modified to support manual review of food articles that do not pass the automated screening processes. Prior Notice requirements will be met through enhancements to the import reporting database.

The web-based electronic prior notice system prototype is on schedule for completion the last week in July. The goal is to have the web-based electronic Prior Notice system and the new ACS–OASIS interfaces operational by the December 12, 2003 deadline.

In fiscal year 2004, FDA has requested $10.5 million of the $20.5 million for operations and maintenance costs of the registration and prior notice systems, for hardware and software maintenance, telecommunications, facility lease, and contract labor. The request also includes funding for operations and maintenance of the labor-intensive paper registration system and combined Help Desk.

Question. How has FDA been working with industry and consumer groups to make sure that these rules are as stringent as necessary while not excessively burdensome?

Answer. President Bush signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—the Bioterrorism Act—Public Law 107–188, into law on June 12, 2002. The Bioterrorism Act requires the Secretary of Health and Human Services, acting through the Food and Drug Administration FDA, to develop regulations by December 12, 2003, to implement Section 305—Registration of Food and Animal Feed Facilities—and Section 307—Prior Notice of Imported Food Shipments. If FDA fails to issue final regulations by December 12, 2003, the Bioterrorism Act still requires domestic and foreign facilities to register with FDA by this date, and requires FDA to receive prior notice of imported food shipments of not less than 8 hours or more than 5 days beginning December 12, 2003. The Bioterrorism Act further specifies that imported food from unregistered facilities, or food offered for import without adequate prior notice, must be held at the U.S. port of entry

until the facility is registered and/or FDA has received adequate prior notice. The Bioterrorism Act requires FDA to develop and issue final regulations by December 12, 2003, to implement section 306—Establishment and Maintenance of Records. FDA is developing a regulation to implement the expedited enforcement procedures for perishable foods required by Section 303—Administrative Detention. Both HHS and FDA are committed to meeting the statutory deadlines in the Bioterrorism Act, and FDA has been devoting extensive resources to this effort.

By typical rulemaking standards, the statutory timeframes for having final rules in effect within 18 months of enactment is an expedited one. To ensure the registration and prior notice rules can take effect by December 12, 2003, FDA is required to propose rules, take comment, and publish final rules within 16 months of enactment. Notwithstanding this ambitious time frame, FDA recognized the significant impact these regulations could have on its stakeholders, both domestic and foreign. Accordingly, FDA began its outreach activities for developing these regulations by issuing a "Dear Colleague" letter to stakeholders, including states, foreign embassies, trade associations, industry, sister agencies, and consumer groups. The letter explained the new regulatory requirements in the Act and FDA's timeline for implementing them. The letter also invited stakeholders to submit comments to FDA by August 30, 2002, that FDA committed to considering as we developed the proposed rules. We requested comments on stakeholders' areas of concern and suggestions for addressing them while meeting the statutory requirements.

In July and August, FDA also held six constituent briefings with stakeholders that approximately 88 organizations, 36 embassies, 52 organizations attended. During these public meetings, FDA explained the provisions in the Bioterrorism Act, and again solicited comments by August 30, 2002. In addition, FDA opened a public docket for each regulation to receive these comments. FDA received over 150 comments during this early comment period that we considered as we developed the proposed regulations. Comments were submitted by 24 trade associations, 8 foreign embassies, 7 foreign countries, 17 individual companies, 8 consumers and consumer groups, and 2 other agencies or state associations. FDA also met with officials at HHS and the Office of Management and Budget, OMB.

Beginning in September 2002, FDA senior staff with responsibility for developing the regulations began weekly meetings with their counterparts within the Department of Treasury, U.S. Customs Service, to discuss implementation of the Bioterrorism Act's provisions, particularly with respect to the registration and prior notice rulemakings. The input we received from Customs is reflected in the proposals that FDA developed.

In September and October 2002, FDA briefed HHS and OMB officials, respectively, on FDA's concepts for the proposed regulations and obtained early feedback before we began drafting the proposed rules. In mid-November 2002, FDA then briefed the other Federal agencies who had stakeholders potentially affected by the proposed rules and/or who had an interest in the safety and security of the U.S. food supply to explain the proposed rules, prior to sending the draft proposed rules to DHHS and OMB. As part of its review under Executive Order 12866, OMB sent both draft rules to other Federal agencies for review and comment, and forwarded all the comments it received from those agencies, as well as its own comments, to FDA for consideration. FDA made changes to the draft proposed rules to address the comments we received.

FDA sent the proposed registration and prior notice rules to the Office of Federal Register on January 29, 2002, where they were placed on immediate display. We also posted the proposed rules on our website on this date. The rules were officially published jointly by FDA and the Department of Treasury on February 3, 2003, 68 FR 5378 and 68 FR 5428, respectively with a 60-day comment period. The comment period closed on April 4, 2003. FDA currently is reviewing the comments and determining what changes should be made to the rules before finalizing them. HHS' and FDA's goal is to publish the final rules by October 10, 2003, which will allow them to take effect under the Congressional Review Act by the statutory deadline of December 12, 2003. FDA can begin accepting registrations from facilities upon OMB approval and the publication of the final regulation so that if FDA publishes the rule as planned, facilities will have 2 months to register before the statutory deadline.

FDA also published notices of proposed rulemaking in the Federal Register to implement sections 303 and 306 on May 9, 2003, see 68 FR 25241 and 68 FR 25187, respectively. The deadline for comment on these proposed rules is July 8, 2003. During the public comment period, members of the public—both domestic and foreign—can submit comments and supporting data for the Agency to consider as we develop the final rules. FDA is committed to working with our stakeholders as we develop all four of these regulations, and we will comply fully with our international trade

obligations, including the applicable World Trade Organization agreements and the North America Free Trade Agreement.

FDA has taken extraordinary steps to reach out to both our domestic stakeholders and our international partners to advise everyone about the proposed rules. To date, FDA senior officials and staff have participated in over 80 meetings, both domestic and abroad. In addition, the Foreign Agricultural Service at the United States Department of Agriculture has held multiple meetings in the countries in which they are located to explain the new requirements. Other international organizations, such as the Inter-American Institute for Cooperation on Agriculture in Costa Rica, also have held meetings using FDA's documents and other outreach materials. We have received numerous compliments from all affected parties on our efforts to reach out to affected stakeholders, explain the new requirements in the Bioterrorism Act and FDA's proposed rules implementing them, and to solicit their comments.

FDA began by holding a public meeting, via satellite downlink, to discuss the registration and prior notice proposed regulations on January 29, 2003, 1:00–3:00 p.m. EST. Nearly 1,000 participants in North and South America, and the Caribbean viewed the live broadcast. The meeting was later re-broadcast to Europe to Asia, Africa, and the Pacific. FDA held a similar public meeting, via satellite downlink, to discuss the recordkeeping and administrative detention proposed regulations on May 7, 2003, 1:00–3:00 p.m. eastern standard time. Participants in North and South America, and the Caribbean viewed the broadcast live. The meeting was re-broadcast to Europe to Asia, Africa, and the Pacific. Transcripts of both broadcasts, as well as copies of the videotape itself, are available on FDA's website in English, French, and Spanish.

FDA has developed fact sheets, talking points, and a Powerpoint presentation presenting an overview of the proposed rules in English, French, and Spanish that others may use to help communicate the requirements of the proposed rules. These materials also are posted on FDA's website. In addition, as stakeholders translate these materials into additional languages, FDA posts the additional translations on our website. Currently, there are approximately ten different language versions available for some of these materials, including Ukrainian, Slovene, Serbian, Russian, Romanian, Polish, Hungarian, Czech, Croatian, and Bulgarian.

FDA also has been working with several sister agencies to ensure a broad dissemination of information and outreach materials, specifically those addressing international outreach. These agencies include the United States Trade Representative, USTR, the United States Department of Agriculture, Foreign Agricultural Service, FAS, the Animal, Plant Health Inspection Service APHIS, and the Grain Inspection, Packers and Stockyards Administration, GIPSA, the Department of State, the Department of Commerce, and the Bureau of Alcohol, Tobacco, and Firearms, within the Department of Treasury. This collaboration led to the development of the fact sheets on the legislation and a flyer on registration that were circulated to FAS officers abroad, an informational email and cable to the posts, fact sheets on the two new proposed rules, press releases, transcripts, and a computer disk that FDA will include in packets sent to FAS officers. These materials will be used by embassy staff to actively and aggressively disseminate information on the legislation and the proposed rules at trade shows, industry meetings, and as a regular part of their interaction with our trading partners.

In addition to the above outreach activities, FDA has attended numerous meetings both domestically and abroad during the public comment periods on the rules to ensure both that affected parties are aware of the proposed requirements and can provide meaningful comments to FDA for the agency to consider as we develop the final rules. These interactions have been invaluable for both stakeholders and for the agency to hear firsthand the suggestions from affected parties.

FDA is taking steps to implement the statute with provisions that are as stringent as necessary while not excessively burdensome. During our development efforts at both the proposed and final rule stages, we estimate the costs and benefits for several regulatory options of varying degrees of stringency. These options vary both the number of regulatory requirements and the coverage of the regulation, and provide varying benefits. We published our cost-benefit analyses for many of these options in the proposed rule and solicited comment on them. In response to comments we received during the public comment period that ended on April 4, 2003, we are revising the cost-benefit analysis of some of the options we presented in the proposal and adding some new options. This presentation of options allows FDA and HHS to see the trade-offs between costs and benefits of various regulatory options, which in turn allows them to choose the regulatory option that most completely supports the statutory requirements with provisions that are as stringent as necessary while not excessively burdensome. We also fully consider our obligations under inter-

national treaties and agreements to ensure that we implement the statute in a way that is not more burdensome than necessary.

Also, since the beginning of our regulatory development efforts, FDA has collaborated with U.S. Customs on the implementation of this rule. Both the registration and prior notice proposed rules were co-signed by the Department of Treasury and the Department of Health and Human Services. During our discussions preceding issuance of the proposed rule and as stated therein, Customs had informed FDA that it could not modify its existing Automated Commercial System, ACS, by the statutory deadline to receive the mandatory prior notifications. As a result, FDA began development of a stand-alone system that would receive the prior notices. The two agencies have continued our collaboration, and recently issued a joint press release in which we announced that importers, in most circumstances, will be able to provide the required information to FDA using ACS, making it easier for them to comply with the new law. As we continue our work to finalize the rule, we continue to meet weekly with Customs to streamline the requirements and implementation to the fullest extent feasible in a continued effort to make the rule no more burdensome than necessary.

Question. Are further increases anticipated in future years as these rules go into effect?

Answer. Out-year budget plans have not been developed, and we will continue to balance competing priorities when requesting funding.

During fiscal year 2005, FDA will be implementing its Import Strategic Plan which will mesh with the Prior Notice and Registration Systems. As the Agency gains experience with the Import Strategic Plan, the experience will inform our budget recommendation.

GENERIC DRUGS

Question. Dr. McClellan, last year, the Senate included a $750,000 increase above the President's request in order to decrease the FDA review time for generic drugs, and requested a report on what types of information should and should not be in the FDA "Orange Book." This year, the FDA budget request includes an increase of $13 million to hire additional employees to reduce review times and support the implementation of improved regulations governing generic drug competition. What is the status of the "orange book" report?

Answer. The "orange book" report to Congress is currently in the clearance process. However, on October 24, 2002, the Agency published its proposed rule, "Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed." The comment period has closed and the final rule is expected to publish soon.

In this proposed rule, the Agency proposed to amend its patent submission and listing requirements for NDAs. The proposed rule clarified the types of patents that must and must not be submitted for listing and revised the declaration that NDA applicants must provide when submitting their patents for listing to help ensure that NDA applicants only submit appropriate patents and therefore make the patent listing process more efficient.

The proposal also would revise the regulations regarding the effective date of approval for ANDAs and certain applications submitted under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. If the ANDA or 505(b)(2) application contains a certification that a listed patent is invalid or will not be infringed and the patent owner or NDA holder brings a suit for patent infringement, the approval of that application is delayed up to 30 months while the litigation is on going. Currently there is the opportunity for multiple 30-month stays of approval. The proposal would permit only one opportunity for a 30-month stay per application that will streamline the ANDA and 505(b)(2) application approval process.

Question. What are the specific goals for review times, if this increased funding is provided?

Answer. The proposed increase in the FDA's generics budget will allow FDA to hire 40 experts in its generic drugs program to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. It is our goal to complete review and action upon original generic drug applications, accepted for filing, within 6 months after the submission date 85 percent of the time for fiscal year 2004.

FDA also has begun internal reforms to improve the efficiency of its review process for generic drugs. In particular, FDA is implementing a new system of early communications with generic drug manufacturers who submit applications. FDA

also will provide additional guidance for generic manufacturers preparing and submitting quality, complete applications.

Studies of the FDA processes for new drugs indicate that such communications and guidance can improve drug applications and allow deficiencies to be corrected during the initial review, rather than having to wait for additional review cycles to fix problems. In addition, generic manufacturers have expressed interest in finding ways to improve the quality of their applications, so that more applications can be approved on the first round of review. The new resources and other reforms are expected to reduce the total time to approval for most new generic drugs by 3 months or more over the next 3 to 5 years. Because these changes will generally accelerate the approval for all generic drugs, most Americans who take generic drugs will benefit.

The FDA also will expand its educational programs and partnerships involving generic drugs, to help consumers get accurate information about the availability of generic drugs for their health needs and to help ensure that consumers are aware that FDA-approved generic drugs are as safe and effective as their brand-name counterparts. FDA will also undertake more scientific studies of generic drug "bioequivalence" to expedite the determination of whether the generic copy of a drug works in the same way as the original product, and will enhance monitoring of the safety of generic drugs on the market.

DRUG PRICES

Question. Dr. McClellan, you mentioned several times during your exchange with Senator Dorgan the need for this country to find a way to provide safe, effective, FDA-approved drugs to the American people at a low cost, both through the Medicaid and Medicare programs. Recently, the Supreme Court ruled that the state of Maine could use their power as a bulk purchaser of drugs for Medicaid patients to bargain with drug companies to make cheaper drugs available to the state's non-Medicaid population. Currently, there is some controversy around this decision, and Secretary Thompson has apparently not yet decided what course of action to take. It seems that Maine has perhaps found a way to do just what you suggested in your testimony—providing safe, effective, FDA-approved drugs at a lower cost to its' population. If the Secretary asked for your opinion on whether or not he should allow Maine to do what they have proposed, how would you respond?

Answer. If Secretary Thompson were to ask my opinion on this issue, I would tell him that if he concludes that the Maine proposal is appropriate and legal under the Medicaid and Medicare programs, there is nothing to suggest that the safety and effectiveness of the FDA-approved drugs purchased under the program would be compromised.

PRODUCT RECALLS

Question. Recently, several lots of the popular drug Lipitor were recalled. I have been contacted by constituents, who, upon hearing of the recall, called their pharmacists to determine whether or not their product was included in it, and whose pharmacists were not aware that any product had been recalled. When a product is recalled, what responsibility is held by the FDA, the drug manufacturer, the pharmacists, and others who may be involved in the production or delivery of the drug, in order to make sure that the message gets to consumers quickly?

Answer. FDA assesses each recall situation on an individual basis to determine what type of public notification is necessary, taking into account factors such as the degree of health hazard, the type and scope of distribution, and the likelihood that product remains on the market. At a minimum, FDA publishes a Weekly Enforcement Report that includes a listing of each new recall after it has been classified, which can take some time. This weekly report is made available to the media and is posted on FDA's public web site, www.fda.gov, under the heading "Safety Alerts and Recalls."

When FDA determines that a product being recalled presents a serious hazard to health that requires a public warning, FDA ordinarily gives the recalling firm an opportunity to issue such a public notice, requesting that FDA be given the opportunity prior to its issuance to review and comment on its adequacy. If the recalling firm cannot or does not issue a public warning when deemed necessary by FDA, then FDA issues such a public notice itself. The Federal Food, Drug, and Cosmetic Act does not give FDA the authority to order a drug firm to recall a product or to issue a public warning, so such actions are voluntary on the part of the firm. The nature of the public notice will vary depending on the circumstances. For example, it might be a general public warning through the general news media, either national or local as appropriate, or it might be through specialized news media such

as professional or trade press, or to specific segments of the distribution chain such as pharmacists, doctors, or hospitals. For Class I recalls, which represent the most serious degree of health hazard and usually involve a public warning, the warning notices are also promptly posted on FDA's web site under "Safety Alerts and Recalls."

Recalling firms are usually the company responsible for the distribution of the violative product in interstate commerce. In most cases the recalling firm is also the manufacturer, but it may be a distributor, especially if the product has been imported or distributed by someone other than the manufacturer. The recalling firm has the primary responsibility to issue any necessary public warning as well as issuing the recall notification to their direct accounts, to whom it shipped the product. Direct accounts, generally wholesale distributors, are usually requested to notify their customers—e.g., chain stores—down to the retail level—e.g., pharmacies. Recalls of products that have the potential to present a serious health risk, such as counterfeit drug products, are normally extended to the user or consumer level. In such a case, because recalling firms do not have information on the identity of the consumer, the recalling firm is usually expected to issue an appropriate press release, as described above, to alert the public so that it is aware of the hazard and can take the necessary steps to remedy the situation.

FDA works closely with the recalling firm to ensure that it conducts an effective recall. To this end, FDA may issue a statement on the recall, especially on a prescription counterfeit drug, to warn physicians, pharmacists, nurses, and all other health care professionals, trade groups, and consumers that a counterfeit drug may be on the market. In this situation with counterfeit Lipitor, the distributor Albers Medical Distributors, Inc. issued a recall notice on May 22, 2003, and FDA issued two talk papers on May 23, 2003, and June 3, 2003, to alert the public. In addition, Pfizer, Inc. issued a news release on June 3, 2003, to further notify U.S. pharmacists of the counterfeit Lipitor.

Question. Are there different procedures in place for different types of recalls (i.e. different types of products or the danger posed by the recalled product)?

Answer. Although the basic recall procedures are the same, the specific details on how a recall is handled vary with the circumstances. For each recall, a specific recall strategy is developed by FDA, or by the recalling firm with FDA's review of the adequacy of the strategy. The strategy takes into account factors such as FDA's evaluation of the health hazard, the type of the product and how it is used, the distribution pattern, the degree to which product is expected to remain on the market, the degree to which the product and the deficiency is easily identifiable, and the possible need for continued availability of essential products. For each recall, the strategy addresses the depth of the recall—e.g., wholesale, retail, or consumer level-the possible need for a public warning and what form it needs to take, what method and level of effectiveness checks the recalling firm will conduct at consignees, what audit checks FDA will conduct, and any other recall implementation factors.

The specific strategy and the urgency of a specific recall vary considerably depending on FDA's assessment of the health hazard involved. FDA assigns a numerical recall classification—i.e., I, II, or III-to each particular product recall to indicate the relative degree of health hazard presented by the product being recalled. Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Although the recall health hazard classification heavily influences the recall strategy, the recall classification does not automatically trigger a public warning or a particular depth of recall. For example, although in practice most Class I recalls are determined to warrant a public warning, such a warning may not be appropriate or necessary if the distribution of the article was quite limited, easily identified, and all units can be quickly and effectively retrieved. Some Class II recalls may be found to require a public warning, whereas others may not. FDA would not usually expect Class III recalls to require public warnings, but it is possible a recalling firm might voluntarily issue such a notice on its own volition. Each recall has to be evaluated on a case-by-case basis and decisions on the recall strategy must be appropriate to the particular situation.

MEDICAL GASSES

Question. Dr. McClellan, as I understand it, FDA has now issued one draft guidance that addresses the general good manufacturing practices (GMPs) that apply to the medical gas industry, and is still working on another draft guidance that will be specific to the validation of air separation units (ASUs). Can you tell me the status of your efforts?

Answer. The Agency has issued the medical gas cGMP guidance document and is currently in the process of developing draft guidance on the validation of ASU requirements. The guidance development process will be consistent with the Agency's good guidance practices and will allow for extensive industry input and interaction. In fact, the Agency has already met with the Compressed Gas Association, CGA, on March 7; April 18; June 18; July 11; August 29; November 6, 2002, and on February 12, 2003, to discuss technical ASU validation issues including risk-models. We will continue to meet and solicit the industry's input on technical issues as we develop the ASU guidance document. Once draft guidance is issued, there will be a comment period, and the Agency will review and seriously consider all comments received during the comment period before finalizing the guidance.

Question. Is the FDA utilizing a risk-based approach with respect to both guidances?

Answer. These guidances are based on extensive input and comments received from industry over several years, and includes risk-based thinking on these issues. There will be ample opportunity for comment and meetings with stakeholders before final guidances are developed to ensure that the available scientific evidence is fully considered in our efforts to develop a risk-based approach on this topic.

Question. It is also my understanding that the medical gas industry has developed a consensus risk-based model for ASU validation that will be the basis for a new industry standard. Can you tell me whether FDA plans to use the industry model or perform an independent risk assessment as the basis for the ASU guidance recommendations?

Answer. The Agency has met extensively with the Compressed Gas Association, CGA, and discussed the industry's proposed risk-based model for ASU validation. The agency found those meetings to be very valuable and productive, and a shared understanding was achieved on many issues that will be reflected in the draft guidance that the Agency intends to develop on the subject. The draft guidance will reflect a risk-based approach, including important aspects of the model that was discussed. There will be further opportunities to discuss this matter to ensure that any unresolved issues can be fully considered before the conclusion of the guidance development process.

COLOR CERTIFICATION

Question. I understand that, under the FFDCA, the FDA certified color regulatory program is paid for by an industry user fee. I have been contacted by a company located in Wisconsin that participates in this user fee program. They state that the FDA has moved this program into significantly larger and more expensive space, even though there has been no increase in programmatic responsibilities or staff. Specifically, they claim that while the color certification program used to run out of 10,000 square feet of space at a cost of $20 per square foot, they have moved to a new, 35,000 square foot space at a cost of $52 per square foot. Also, security costs have increased from $10,000 in previous years to over $300,000 this year. Further, it is my understanding that in previous years these companies have received a rebate from the FDA for unused funds, and that these rebates, which some companies had come to depend on, will no longer be given.

What is the justification for moving to this larger, significantly more expensive, space? What is the justification for the increase in the security costs?

Answer. The General Services Administration, GSA, required FDA to vacate Federal Building 8 by December 31, 2002, and to prepare that building for other uses. FDA was forced to set up a temporary location for the color certification function while new space is being made available in College Park, Maryland. GSA had only one facility available for FDA for this purpose in Chantilly, Virginia. The color certification staff moved from Federal Building 8 to the interim space in Chantilly, Virginia in October 2002. While the Federal Building 8 space housed a majority of CFSAN staff including color certification, the Chantilly space is solely for work done by the color certification staff. The interim space provided by GSA is larger than FDA requested; unfortunately, there is not an easy way to divide the space so that FDA could use less. FDA's Associate Commissioner for Management and Systems visited the space to review the situation. In fiscal year 2003, FDA will have to use funding in the color certification account to pay for approximately $1.8 million in

rent and related costs for the Chantilly location and about $1.5 million for buildout for College Park. The first phase of the move of the color certification operation from Federal Building 8 to interim space in Chantilly, Virginia took place November 2002 and the second and final phase was completed in December 2002. FDA senior management has met with industry staff more than once to review these costs.

When the color certification program was housed at Federal Building 8, a proportionate share of security services at Federal Building 8 was applied to the color certification program. In contrast, the interim office in Chantilly is used only for the color certification program. In fiscal year 2003, after the events of September 11, all Federal facilities have new security requirements. For both of these reasons the security costs applicable to the certification function have risen significantly.

The fees for certification of colors have not been raised since 1993. Consequently, FDA's fee income for this function has been relatively steady. Naturally, as the employees receive pay raises, and as general inflation affects other costs, FDA's costs tend to rise gradually over time. During fiscal year 2002, FDA made a refund to the industry of $1 million in fees that had been collected over a period of years but were not needed by the agency at that time. This was in part due to the fact that FDA's rent costs related to this function were reduced in fiscal year 2001 due to GSA reducing the overall rent cost for Federal Building 8; the costs to this fund were reduced further in fiscal year 2002 because GSA did not charge FDA rent for the building, but only utilities costs and other costs of operating the building. Combined, this Fund saved about $800,000 in space costs during fiscal years 2001 and 2002 due to these cost reductions.

In fiscal year 2003, however, FDA has had to incur significantly higher rent costs for a temporary laboratory for this function in Chantilly, VA, and has also had to provide funding to GSA for the buildout costs of a building in College Park, Maryland, near the present Harvey Wiley building occupied by FDA. This additional building is being prepared to house the color certification function on a permanent basis.

While FDA currently expects to have sufficient funds in this account to be able to absorb these costs during fiscal year 2003, the agency will not have any funds with which to make any refund to the industry. It should also be noted that refunds of fees are not a regular event—before the refund made during fiscal year 2002, the last prior refund was in 1990.

Question. What effect is this going to have on the amount of the user fees that the color certification industry is required to pay?

Answer. For fiscal year 2002, the fee income in this fund was about $5 million, and expenses were only about $4 million because the fund had very low costs for space since the agency was not being charged rent for Federal Building 8. However, in fiscal year 2003, we expect total expenses to be about $7.5 million, while income remains around $5 million. Therefore, most of the surplus money in this fund will be depleted. For fiscal year 2004, projected expenses for this activity are estimated at about $6 million. The agency expects to need to raise the fees for color certification, because the current level of income is not enough to meet the costs of the function on a continuing basis.

Question. As the sole provider of funding for this new space, was the industry consulted prior to the move?

Answer. Yes. FDA senior management has met with industry staff more than once to review these costs. In fact, when FDA staff met with industry representatives prior to the refund that was made to industry during fiscal year 2002, we explained that there would be some substantial costs due to this necessary relocation of the program. At the meeting industry representatives were notified that we would be moving to interim space and funds to cover buildout costs for the permanent facility would also be required.

Question. Do you believe the sole responsibility for paying for what, at first glance, appears to be unnecessary increases in space and security costs, should lie with the color certification industry?

Answer. The law requires that the fees support all costs of the color certification function, and the agency is using fees that have been built up in this account to meet the increased facilities costs being incurred in fiscal year 2003. The agency did make a refund to the industry of $1 million during fiscal year 2002, but it is not possible to make another refund now during fiscal year 2003 without jeopardizing FDA's ability to keep a reasonable amount of funds in this account to assure continued service to the color industry. The agency expects to have a balance in this account on September 30, 2003, of only about $1 million in total.

Question. How has the FDA responded to the concerns of the color certification industry?

Answer. FDA senior management has met with industry staff more than once to review these costs. In fact, when FDA staff met with industry representatives prior to the refund that was made to industry during fiscal year 2002, we explained that there would be some substantial costs due to this necessary relocation of the program. Also, it is likely that the fees will need to be raised at some point during fiscal year 2004, and the agency has informed the industry's representatives of that likelihood. During a meeting with industry representatives in December 2002, all costs for the program were explained.

Question. What is the FDA's plans regarding a rebate for this industry, and if one is not going to be provided, why?

Answer. During fiscal year 2002, FDA made a refund to the industry of $1 million in fees that had been collected over a period of years but were not needed by agency at that time. This was in part due to the fact that FDA's rent costs related to this function were reduced in fiscal year 2001 due to GSA reducing the overall rent cost for Federal Building 8; the costs to this fund were reduced further in fiscal year 2002 because GSA did not charge FDA rent for the building, but only utilities costs and other costs of operating the building. Combined, this Fund saved about $800,000 in space costs during fiscal years 2001 and 2002 due to these cost reductions.

In fiscal year 2003, however, FDA has incurred significantly higher rent costs for a temporary laboratory for this function in Chantilly, VA, the only facility GSA had available for this purpose. FDA has also had to provide funding to GSA for the buildout costs of a building in College Park, Maryland, near the present Harvey Wiley building occupied by FDA. This additional building is being prepared to house the color certification function on a permanent basis.

While FDA currently expects to have sufficient funds in this account to be able to absorb these costs during fiscal year 2003, the agency will not have any funds with which to make any refund to the industry. It should also be noted that refunds of fees are not a regular event—before the refund made during fiscal year 2002, the last prior refund was in 1990. Also, it is likely that the fees will need to be raised at some point during fiscal year 2004, and the agency has informed the industry's representatives of that likelihood.

BLOOD SAFETY

Question. Dr. McClellan, according to a December 2002 Associated Press report, FDA found more than 200 safety violations by the blood-collecting unit of the Red Cross, and has asked a court to hold the Red Cross in contempt for several years of safety violations. It is my understanding that FDA and the Red Cross are now working to improve the safety standards of the Red Cross. Can you please provide me with information on how FDA is working with the Red Cross to improve their safety standards?

Answer. Since May of 1993, the American Red Cross-ARC-has been under a Consent Decree of Permanent Injunction that required ARC to establish clear lines of managerial control over a newly established comprehensive quality assurance system in all regions; to enhance training programs; and to improve computer systems, records management, and policies for investigating and reporting problems, including adverse reactions. In August 2000, concerns arising from an inspection of ARC's national headquarters for blood services revealing that ARC had not adequately corrected serious violations of blood supply rules recurring over the past 17 years prompted FDA to begin negotiations with ARC to revise the 1993 Decree.

After extensive discussions and mediation efforts, ARC agreed to sign an Amended Consent Decree of Permanent Injunction, containing substantial revisions to the original Consent Decree designed to improve safety standards at ARC. The Amended Consent Decree, which the United States District Judge signed on April 15, 2003, is the culmination of these negotiations.

The Amended Consent Decree includes the important substantive provisions from the original Decree, and updates them to provide a series of clear deadlines for completing specific requirements of the Decree. Importantly, the provisions were also revised to address additional types of violations observed since the original Decree was signed in 1993. The Amended Decree also includes a comprehensive financial penalty scheme that requires ARC to pay substantial financial penalties if, in the future, ARC fails to comply with FDA laws and regulations aimed at ensuring the safety of the Nation's blood supply.

FDA expects that ARC will concentrate fully on responding to the Agency's concerns about blood safety, and to its responsibilities as a major supplier of the Nation's blood, by implementing the systems required by the Amended Consent Decree. By doing so, ARC will avoid the need for FDA to use financial penalties to force

ARC to improve its operations, to promptly correct problems when they are discovered, and to take action proactively to prevent further violations from occurring.

HOMELAND SECURITY

Question. How many FTEs are currently on detail to the Department of Homeland Security?

Answer. No FDA staff are on detail to the Department of Homeland Security. However, FDA is working extensively with the Department of Homeland Security. We participate in regular interagency meetings with DHS on food security issues and also agriculture security issues that involve the Department of Agriculture.

Question. How long is the average detail to DHS?

Answer. Currently, FDA does not have any employees detailed to the Department of Homeland Security.

Question. What effect, if any, is this having on the workload of employees at FDA? Are there effects on performance?

Answer. The workload of FDA employees and Agency performance levels will not be affected by work being conducted in collaboration with the Department of Homeland Security.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

SHELLFISH

Question. Two years ago the GAO reported to Senator Lugar and me about the failure of FDA and the Interstate Shellfish Sanitation Conference to adequately protect consumers from unsafe shellfish. The FDA continues to fund campaigns to educate vulnerable consumers about avoiding raw Gulf Coast shellfish that may be contaminated by deadly Vibrio vulnificus bacteria. Those efforts have failed, in part because they failed to inform consumers which shellfish were safer to eat, such as those harvested from colder waters or even Gulf Coast shellfish that were processed to eliminate deadly bacteria. Will you work with the ISSC to ensure that future campaigns will inform all consumers that raw shellfish harvested from cold waters and processed Gulf Coast shellfish are safer than raw, unprocessed Gulf shellfish harvested during warmer months?

Answer. We continue to believe that immuno-compromised individuals should avoid raw animal protein generally, including raw molluscan shellfish. Immuno-compromised persons should only eat molluscan shellfish that are fully cooked because there can be viruses or other pathogens in raw seafood that are potential risks to immuno-compromised persons in addition to Vibrio vulnificus. Consequently, FDA education efforts and the current Interstate Shellfish Sanitation Conference, ISSC, education efforts advise immuno-compromised individuals to avoid raw molluscan shellfish.

Moreover, the issue of differentiating some oysters from others is complicated. For example, we have been working with ISSC to increase the number of oysters that have been processed to kill Vibrio vulnificus. However, we have been advised by the ISSC that doctors in Texas declined to dispense ISSC education materials that suggested that their immuno-compromised patients could safely eat oysters that had been processed to kill Vibrio vulnificus. These doctors insisted that their patients completely avoid raw shellfish. We continue to consider the question of how to be supportive of new technologies, such as post harvest treatments, that kill Vibrio vulnificus while at the same time fully protecting immuno-compromised individuals.

METHYLMERCURY

Question. Eight percent of U.S. women of childbearing age have mercury levels in their blood that are high enough to raise concerns. Although the FDA is responsible for ensuring the safety of commercial seafood, it currently conducts little monitoring of mercury levels in seafood and does not focus on the species, like tuna (canned and fresh), that are most popular with consumers. When will FDA establish a comprehensive plan to monitor mercury levels in a wide variety of fish, especially popular species? Does the agency have the resources to test mercury levels in a statistically significant number of tuna and other popular species?

Answer. FDA is conducting a study to measure mercury levels in a variety of 12 different domestic and imported commercial fish. This study is designed to augment the current data set FDA has on mercury levels in fish. Most of FDA's monitoring of methylmercury in commercial seafood has been undertaken as part of the Total Diet Study. The Total Diet Study, sometimes called the Market Basket Study, is an on-going FDA program that determines levels of various pesticide residues, contami-

nants, including methylmercury, and nutrients in foods. The purpose of the study is to estimate the intake of these substances in representative diets of specific age-sex groups in the United States to determine potentially unsafe dietary conditions. To accomplish this goal, FDA purchases foods from supermarkets or grocery stores four times per year, one from each of four geographic regions of the country. The most frequently consumed foods are collected based on food consumption data. Therefore, those fish most frequently consumed are those that are tested.

LISTERIA MONOCYTOGENES

Question. Listeria monocytogenes causes 2,500 illnesses and 500 deaths each year, according to the Centers for Disease Control and Prevention. More than 3 years ago, FDA committed to amend its regulations to better protect consumers from Listeria in smoked seafood, fresh cheeses, and other FDA-regulated ready-to-eat foods. When will you issue a proposed rule to require Listeria testing in facilities that produce ready-to-eat foods? Do you have the resources to expedite this rulemaking?

Answer. Listeria monocytogenes, LM, a harmful bacterium that can be found in a variety of foods, causes an estimated 2,500 illnesses and 500 deaths in the United States each year. In pregnant women, LM-caused illness can result in miscarriage, fetal death, or severe illness in or death of a newborn infant.

The Department of Health and Human Services and the U.S. Department of Agriculture have reviewed ongoing LM prevention and control activities and developed a joint action plan in 2001, which includes immediate, short-term, and long-term activities targeted at the serious problem of LM-caused illness. The Plan can be found at the following internet address, http://www.foodsafety.gov/dms/lmriplan.html.

The action plan is a multi-pronged collaborative effort to decrease the number of cases of human listeriosis. The plan takes into consideration the results of the DHHS and USDA draft risk assessment of foodborne LM in ready-to-eat foods, which was published in January 2001 along with the draft LM action plan.

FDA plans to issue the final risk assessment and model during the summer of 2003, and the draft LM action plan will be updated accordingly based on this new information. Some of the on-going items include expanding PulseNet to enhance consumer and health care provider information and enhance disease surveillance and outbreak response. Some of the items being considered for the future include continuing education efforts, issuing draft FDA guidance for food processors, redirecting regulatory strategies, working with other Federal agencies on safety-based date labeling and coordinating research activities on the development of better methods of detection and quantification of LM.

Following the publication of the final LM Risk Assessment, we will determine where we need to focus our efforts to protect the public health.

QUESTIONS SUBMITTED BY SENATOR TIM JOHNSON

TISSUE REGULATIONS

Question. I understand that FDA has delayed regulation of the human tissue transplant market for more than 6 years, even though the agency acknowledges that the use of infected tissues poses a serious threat to public health. During a recent Governmental Affairs hearing, the FDA Director of the Center for Biologics Evaluation and Research said that FDA will adopt new rules for tissue banks, but did not indicate when. While the implementation of such regulations continues to be delayed, people are dying as a result of receiving contaminated tissues Commissioner. What I would like to know is, what exactly is your time line for rolling out regulations for the tissue transplant industry?

Answer. FDA has had regulations in place for some human tissues since 1993. These regulations require tissue establishments to test human tissue donors for HIV–1, HIV–2, hepatitis B, and hepatitis C; prepare and follow written procedures for disease testing, assessing relevant medical records, and identifying quarantined tissue; prepare, validate and follow written procedures for prevention of infectious disease contamination or cross-contamination by tissue during processing; and, maintain records. The regulations also authorize FDA to inspect tissue establishments, to quarantine imported human tissue, and to require retention, recall, and/or destruction of violative tissue. FDA considers these rules to be an interim measure, until FDA finalizes the more comprehensive regulatory scheme developed in FDA's tissue action plan.

Implementation of the tissue action plan is a top priority for the Agency at this time. We are in the process of finalizing a proposal for review and clearance by the Administration. Though we do not have a precise target date for publication of the

final rules, you can be sure that it is a top priority for Dr. McClellan and Dr. Goodman.

MEDICAL DEVICE USER FEES

Question. The MDUFMA user fee agreement was designed to create a stable and sufficient funding base for the rapidly expanding portfolio of increasingly complex devices that CDRH must regulate and approve. As Chairman Bennett pointed out at the hearing, substituting user fee money for budget money essentially amounts to a tax increase on innovation. If you combine $15,150,000 in user fees to a $6,000,000 drop in the fiscal year 2004 base funding for CDRH proposed by the Administration, doesn't the overall CDRH budget increase by a total of only $9,150,000 in the Administration's proposed fiscal year 2004 budget? Isn't this the type of budget gimmick that the user fee trigger was designed to avoid? Why does your budget request prioritize millions of dollars of discretionary spending over the requirements of the MDUFMA law?

Answer. One of the provisions of MDUFMA requires that the funds from fees must be in addition to an appropriation amount that is as great as the amount FDA spent on the device review process from appropriations in fiscal year 2002—the year before MDUFMA went into effect—adjusted for inflation. This provision is meant to ensure that appropriated resources available for device review are increased for inflation each year, and that the funding from fees is over and above a set level of appropriations, after adjustment for inflation. We are committed to working within the Administration and with Congress to ensure that the intent of MDUFMA is realized. The reductions for the Device and Radiological Health program reflect management savings and IT consolidation and should not impact the resources directly devoted to the review process. User fee collections under MDUFMA are not considered an offset for this program. They are used exclusively for the review of new devices and related costs. FDA supports the goals of MDUFMA, and is committed to making the medical device user fee program a success.

Question. If Congress does not appropriate the remainder of the $45 million MDUFMA target for CDRH budget, the user fee program will end and FDA will face the loss of up to $35 million per year in user fee money. This would create a dramatic revenue loss for CDRH and FDA, and cause patients to wait longer for the approval of new devices. What mechanisms does FDA have in place to assure that this will not happen?

Answer. The agency looks forward to working with Congress and industry to ensure the device user fee program is successful. FDA is committed to meeting the performance goals, as stated in the goals letter. We have already begun discussions within the Administration to find ways to fund this program appropriately in fiscal year 2005 and beyond to ensure that this important program does not sunset. FDA is committed to the goals of the Medical Device User Fee program and we are committed to finding a way to make the MDUFMA program work, to make it sustainable, make it permanent, and avoid having the trigger kick in because we are meeting our performance goals.

GENERIC DRUGS EDUCATION

Question. In fiscal year 2002, this committee appropriated $250,000 for the Office of Generic Drugs to do outreach and education on the safety and efficacy of generic drugs. What is the status of these activities at this point and where do you hope to go in the future in this regard?

Answer. FDA has embarked on a multimedia educational program to build consumer and health-care professionals' confidence in the safety and effectiveness of generic drugs. The primary audience for the educational program has been consumers. The messages being conveyed are that generic drugs are reviewed and approved by the FDA, and that they are safe, effective and manufactured under FDA's quality standards. FDA has developed and distributed three print public service announcements, brochures, newspaper articles, and an FDA Consumer Magazine article.

Congress recommended an additional $150,000 for this program in the fiscal year 2003 appropriation and FDA expects to spend this amount by the end of the fiscal year. With these funds FDA has also pursued the possibility of expanding the audience for this campaign by conducting focus groups for pharmacists and physicians.

In fiscal year 2004, $400,000 has been proposed to support the generic drug education program for its third year. The work for fiscal year 2004 is building upon plans previously established to further communicate a standard message for the public. These funds will be used to continue support for FDA's multimedia educational program to build consumer and health-care professionals' confidence in the safety and effectiveness of generic drugs. FDA will continue to convey the message

that generic drugs are reviewed and approved by the Agency, and they are safe, effective and manufactured under the Agency's quality standards. The campaigns will continue to include the distribution of print public service announcements, brochures, newspaper articles, and FDA Consumer Magazine articles. In addition, funds will be used to take information from focus groups for pharmacists and physicians to develop educational programs for those professionals.

DRUG COUNTERFEITING

Question. I know that you are concerned about the quality and safety of prescription drugs re-imported from Canada, yet as you know, we are learning more and more about the problem of drug counterfeiting inside U.S. borders. Pharmacists are worried because some of the fakes are so good it is hard to tell what is counterfeit and what is real. Part of the problem appears to stem from the quick expansion of the secondary wholesaler industry. I was shocked to hear in a recent article on this issue that a drug might be bought and sold up to 6 or more times before reaching the consumer. Most wholesalers are doing a good job, but counterfeiting by a few bad eggs is becoming an increasing problem, which really concerns me. What is FDA doing to better monitor drug counterfeiting and diversion within the United States? What specific plans does FDA have to increase regulation of the secondary drug wholesaler market?

Answer. The overall quality of drug products that consumers purchase from U.S. pharmacies remains high. The American public can be confident that these medications are safe and effective. FDA cannot, however, offer the same assurance to the public about the safety and quality of drugs purchased by consumers from foreign sources.

FDA takes very seriously any allegations or information regarding the counterfeiting or adulteration of drug products. As the drug manufacturing and distribution system has become more global in nature, the challenge of protecting against counterfeit, adulterated or substandard drugs has become more difficult. The Agency is concerned about a spate of drug counterfeiting and tampering cases that have occurred in recent months, and is aggressively pursuing these types of enforcement cases.

FDA is working on a number of fronts to address the influx of unapproved and counterfeit prescription drugs coming into the United States from foreign sources. These efforts include: educating the public to the significant potential safety issues presented by the purchase of drugs from foreign countries; working with professional groups to disseminate FDA's message on the potential dangers of Internet drug sales; partnering with state governments and other Federal agencies to develop more effective enforcement strategies; and, undertaking monitoring of and enforcement against Internet pharmacy outlets that present the most significant concerns. Recent high-profile regulatory actions send a strong message that FDA is actively working to take strong steps to protect the public from conduct that threatens the U.S. drug supply.

The Agency has responded to the challenge of counterfeit drugs and diversion in the secondary market by employing a risk-based enforcement strategy to deploy our existing enforcement resources in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. As an example, the Agency utilizes Import Alerts to identify particular shipments that may pose significant potential risk to public health. In the case of the increased volume of unapproved sildenafil, also known as generic Viagra, arriving at the Miami facility, the Agency has issued an Import Alert to instruct field personnel to work with the BCBP to detain all such shipments from specific manufacturers, distributors and countries of origin.

FDA is also developing an new initiative on counterfeit drugs which includes creating an internal task force to explore the use of modern technologies and other measures such as partnering with State and Federal law enforcement agencies for stronger enforcement that will make it more difficult for counterfeit drugs to get distributed with—or deliberately substituted for—safe and effective drugs.

FDA's Office of Criminal Investigations, or OCI, works with state and other Federal investigative agencies and prosecutors to uncover violations of the FD&C Act and other laws with respect to unapproved, misbranded, illegally imported, or otherwise unsafe or substandard drug products.

OCI has opened 73 counterfeit drug cases since October 1996. Investigations have so far netted 44 arrests and 27 convictions. Fines and/or restitution have been imposed in excess of $250,000. FDA has seen a gradual, but troubling, increase in the incidence of finished dosage form counterfeit activity. Much of this activity has targeted high volume, high cost drugs where counterfeiters attempt to obtain the highest return possible in a short time period. Many of these drugs are used for treating

cancer and AIDS patients. The public perception of a more dramatic increase in counterfeit drug activity stems from the fact that the latest several counterfeits have appeared in the wholesale market and received wider distribution than has been the case historically.

On April 22, 2003, the Pharmaceutical Research and Manufacturers of America, or PhRMA, which represents the country's major research-based pharmaceutical and biotechnology companies, announced the adoption of a voluntary program to report suspected instances of drug counterfeiting to FDA. The information provided by PhRMA members under this program will be helpful to the Agency because it will assist FDA in carrying out its responsibilities to protect the safety and integrity of the Nation's drug supply by enhancing the Agency's ability to detect quickly and remove counterfeit drugs from the marketplace.

Under this program, PhRMA member companies have agreed to notify FDA's OCI within 5 working days of determining that there is a reasonable basis to believe that a product has been counterfeited. The program also applies to counterfeits discovered in foreign countries if there is clear evidence that the counterfeits are intended for distribution in the U.S. Drug manufacturers already conduct their own investigations of suspected distribution of counterfeit drugs. This formal collaborative agreement will strengthen FDA's ability to assure the safety and effectiveness of drugs used by U.S. Consumers. The reporting program went into effect on May 1, 2003.

ADDITIONAL SUBMITTED STATEMENT

CLERK'S NOTE.—The Subcommittee has received a statement from the Medical Device Manufacturers Association which will be inserted in the record at this point.]

PREPARED STATEMENT OF THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION

We would like to thank the Subcommittee for the opportunity to submit comments on the subject of medical device user fees. The Medical Device Manufacturers Association (MDMA) is a national trade association based in Washington, D.C. that represents and serves the innovators and entrepreneurs in the medical device industry. The thousands of innovative companies that MDMA represents, including over 160 dues paying members, consist of manufacturers of medical devices, diagnostic products, and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of innovative products in the marketplace.

The device user fee program has been an area deep concern for our members since the Medical Device User Fee and Modernization Act (MDUFMA, Public Law 107–250) was signed into law in October 2002. As you know, we are philosophically opposed to the idea of device user fees; however, we intend to meet our obligations under the agreement negotiated in MDUFMA.

MDUFMA was designed to provide an enhanced and expeditious review process for medical devices by imposing fees on premarket approval applications, supplements, and 510(k) submissions reviewed by the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA). The law provides for shared responsibility between manufacturers and the government to fund the program. Over 5 years, the manufacturers' fees and Congressional appropriations would provide CDRH with $225 million in additional resources in exchange for strong new review performance goals for the agency. The performance goals set out in the letter accompanying the bill are conditioned on FDA receiving money from both industry and Congress. Thus, without adequate Congressional support, manufacturers will not see the benefits from their user fee payments.

While MDUFMA ensures industry funding of $81 million over 3 years, with additional industry funds in later years if the program continues, the performance goals agreed to in MDUFMA are conditioned on FDA receiving an additional $45 million in federal appropriations during the first 3 years of the program (fiscal years 2003–2005). If Congress fails to appropriate these funds, the program will sunset in fiscal year 2006, without industry receiving the improved review times agreed to in MDUFMA. Without the additional Congressional appropriations, device manufacturers fear that their user fee contributions over the next 3 years will not have the desired effect of more expeditious reviews.

To fully fund the FDA and allow them to meet the performance goals included in MDUFMA, Congress would need to appropriate $205,720,000 for CDRH for each of fiscal years 2003–2005, with inflationary adjustments. So far, Congress has not

provided the needed support. In fiscal year 2003, the appropriation for CDRH was $194,720,000, which represents only a $4 million increase from the fiscal year 2002 figure—not even enough to cover salary increases—and leaves CDRH $11 million short of the fiscal year 2003 target of $205,720,000. This shortfall needs to be made up in the next 2 years to avoid the program's sunset. If Congress maintains the fiscal year 2003 level in fiscal year 2004, the funding level will be $22 million in deficit.

Potentially making matters even worse, the President's fiscal year 2004 budget request for CDRH is $184,543,000, more than a $10 million cut from the actual fiscal year 2003 appropriation. Cutting the budget by this much would result in a $32 million shortfall leading up to fiscal year 2005, not including inflationary adjustments. Potentially there would be a need for a $50 million plus appropriation in fiscal year 2005 in order to maintain the user fee program.

Recent statistics show that the FDA device reviews are still taking far too long. The average approval time for premarket applications is 364 days—more than twice the statutory target of 180 days. In addition, approval times for 510(k)s are on the rise, up to a 96-day average. MDUFMA performance goals would require FDA to approve 90 percent of PMAs within 320 days by 2007. This will not be attainable unless FDA receives the additional Congressional appropriations authorized in MDUFMA. Furthermore, a massive third year appropriation would not be a reasonable solution. FDA needs this money this year so that it will have the ability to hire the staff needed to meet the performance goals.

We recognize that Congress must make difficult decisions among many competing spending priorities. However, we encourage Members to consider the importance of supporting faster FDA reviews of innovative devices. Many of these devices present significant scientific advancements that need to be brought to the health care market as quickly as possible. Diagnostic products and other innovative technologies for use by public health workers are especially timely, though these technological breakthroughs are of little use if the FDA cannot review them in a timely fashion. Bottling up new devices in the FDA review pipeline only serves to harm patients who could benefit from access to the latest treatments and devices.

Congress should be committed to appropriating adequate resources to ensure that new products can get to the market as quickly as possible. MDMA is working to ensure that Congress appropriates the money now so that patients will have access to innovative products faster through improved review times. We strongly encourage the Subcommittee to appropriate the funding amounts established in MDUFMA so that the FDA will be able to achieve the performance targets that device manufacturers are currently paying for.

Without adequate Congressional support, the intent of MDUFMA will fail completely. Now that industry is "paying in" in the form of a user fee, manufacturers should receive something in return. The industry's $81 million contribution in fees over the next 3 years should result in receiving the benefit of improved performance goals. However, if Congress does not meet its obligations as agreed to in MDUFMA, MDMA will not support future user fee proposals.

MDMA thanks the Subcommittee for the opportunity to present our views on this matter, and we look forward to working with you in the future to continue to improve the FDA to ensure that patients have access to the latest in medical technology.

CONCLUSION OF HEARINGS

Dr. MCCLELLAN. I agree with that.

Senator BENNETT. Thank you very much.

Dr. MCCLELLAN. Thank you, Mr. Chairman.

Senator BENNETT. The subcommittee is recessed.

[Whereupon, at 12:13 p.m., Thursday, May 22, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]